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Vol II. Case Studies

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Foreword

One of the key aspects of any document that provides guidance is to put its contents into practice, in order to show the way in which a specific topic should be applied. This is why the Federal Commission of Regulatory Improvement (COFEMER) requested information on specific applications of methods and methodologies to the economies in the Asia-Pacific Economic Cooperation (APEC) who participated in this Project, in order to be able to develop guidelines on the use of methodologies to evaluate the impact of regulations.

Volume II of the Regulatory Impact Evaluation Guide contains case studies provided by the economies during their participation in the three Workshops and even in the time between these events. These are real life experiences of authorities from all the participating economies who faced great challenges in order to evaluate the specific impacts that arose from regulatory proposals.

This Volume is the product of the continuous support from all of the authorities that participated in the workshops and it would not have been possible without the effort and time they put into the development of these case studies. There are no words enough to express our deep gratitude to all of them since their contributions have made this Guideline very exhaustive.

These case studies show the real application of many of the methods and methodologies explained in the Volume I of the Guide, and they intend to provide further guidance to officials from APEC economies that are in charge of conducting evaluations of the impact of regulations. Its ultimate purpose is to aim in the development of high quality regulations with benefits for society.

Once again, this is the result of a joint effort. It shows the enormous value of regulatory cooperation and it should pave way for further collaborations that may derive in tools and good regulatory practices that will support the future developments in this area. The exchange of experiences among APEC economies is probably one of the key aspects that may help us become more developed economies and provide better quality of life to our citizens. This is why we will keep reaching out to Asia-Pacific economies in order to enhance cooperation efforts that could serve to these common objectives.

Virgilio Andrade Martínez
Head of COFEMER

Acknowledgments

We appreciate the public servants dedication in the development and translation into English of the cases presented in this Volume. We are sure that the knowledge contained in ***Volume I. Methods and methodologies*** is reinforced with this ***Volume II. Case Studies.***

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México City, February, 2014.

INDEX

Matter of regulation	**"Regulatory Standard for Safety Requirements in Commercial Trampolines" (AS 4989—2003, Standards Australia Committee)**

Type of regulation *(choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology (**X**) Cost of illness method (**X**) VSL (**X**) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	( ) Sensitivity analysis ( ) Immediate Rate of Return (**X**) Other, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal Rate of Return

Case 1. Regulatory Standard for Safety Requirements in Commercial Trampolines

A. Introduction

In 2010, the Minister for Fair Trade of New South Wales, Australia, asked the former Minister of Regulatory Competition and Consumer Affairs to consider developing a national regulation for safety of domestic trampolines. This was followed by an investigation by the New South Wales Product Safety Commission (NSW PSC), which considered whether the use of domestic trampolines should be prohibited or allowed under certain conditions or restrictions. The information collected in the course of this investigation is the source of much of the content included in this regulation draft. Thus, the Australian average trampolines have accepted the proposal to revise the standard AS4989-2006, where the study includes assessment of the introduction of safety net enclosures in the Australian standard.

B. Identification of the problem

Injury data and research shows that children suffer more injuries from impacts with hard parts of the trampoline, as the frame system and the suspension (including steel springs that connect the pad to the frame). Most domestic trampolines are provided with padding in the chassis and suspension systems, but there is evidence to suggest that, in many cases, this filler does not meet the requirements to fulfill the impact mitigation established in the Australian regulation, thereby increasing the risk of injury to users. Moreover, children are also affected by hitting the ground after falling from domestic trampolines. Currently there are not stringent legislative requirements related to domestic trampolines in Australia, as a result many of the domestic trampolines do not have a stuffing system in the suspension and the frame, or the stuffing supplied does not meet the appropriate safety requirements.

The Australian Standard AS4989-2003 related to the safety of trampolines was published in 2003. The standard was developed to address the injuries associated with trampolines. It establishes the requirements for the components and design, as well as the information needed to specify the assembly and maintenance. In 2006, the standard (renamed as AS4989-2006) was revised to eliminate the design specifications of the structure and focus on other aspects such as safety, stuffing design, sharp edges and adequate warnings targeting consumers. Nevertheless the standard still does not address properly the risk of children falling off the trampoline in the sense that a number of national suppliers provide safety nets with their trampolines as a security measure to reduce the risk of user falling off, this is not a requirement in the current standard.

The data and statistics provided by health sources in New South Wales, Queensland and Victoria suggest that, in these states, **about 3,000 children are annually reported injured as a result of the trampoline use.** Data from the Australian Bureau of Statistics (ABS) suggest that the combined population of New South Wales, Victoria and Queensland makes up 77% of the Australian population. So it is reasonable to assume that the injury rate in other states is similar to that of these states.

The investigation and analysis conducted by the Victoria Injury Surveillance Unit (VIISU) show that, over a period of eight years, from 2002 to 2009-2010, in Victoria, the total

number of injuries related to trampolines was 11,857. Of these, 77% (9,184 cases) were caused by trampoline falls, inside and outside. The VISU data categorized the "location of injuries," which is: "at home," "other particular place" and "undetermined place." The location of the injuries related to the trampoline falls specifies that 88% occurred at home. In Victoria, hospital treatments of injuries related to trampolines averaged 1,148 annual cases in the eight years period, these injuries steadily increased during the period (there were 945 injuries related to falls in 2004-2005 and 1,531 in 2009-2010). These statistics come from the hospital records of the city of Victoria.

The above information identified a safety problem as a result of a **government failure** arising from the lack of an appropriate regulation that warrants the safety of children while using trampolines. In order to overcome this government failure is necessary a government intervention.

C. Objectives of the intervention

The Government's intervention main objective is to reduce the number and seriousness of injuries suffered by children as a result of an impact with the domestic trampolines chassis and suspension systems.

The ideal goal is to eliminate the damage caused by a fall on the suspension system and/or the frame of a trampoline. Unfortunately, due to the nature of the trampoline use, it is likely that injuries caused by impact with the frame and suspension systems continue, but the regulation aims to reduce the rate of accidents and the severity of injuries, at least.

D. Regulatory alternatives

The viable alternatives to achieve the objective and overcome the identified government failure are:

- ***Baseline scenario (maintaining the status quo)***.

That is, keeping current industry practices and looking for the voluntary compliance of the Australian Standard as well as influencing consumer education. This means that the identified problem will keep happening and safety of children while using trampolines will still be in risk.

- ***Government regulatory proposal on safety standards and consumers' education.***

Australian Government aims to solve the safety problem through the update and adequacy of the voluntary standard AS44989-2006. It includes the following relevant safety requirements for the risks referred:

- Protection against impact on the suspension system.
- Properties for the frame and suspension system to mitigate the impact, where the frame and suspension system are at the same level.
- Properties of impact mitigation on the "soft edge system," where the frame and suspension system are not at the same level.

In this sense, the regulatory proposal covers the following requirements specified in The Standard:

- The suspension system must be designed to protect the user from injuries resulting from contact with edges and it should be resistant enough to support the loads allowed without any permanent deformation.
- Cushioning systems are required for the frame or suspension systems in domestic trampolines.
- Cushioning systems must be safe.
- Cushioning systems must completely cover the surface of the frame and the suspension system.
- The cushioning of the frame must meet the requirements on bumps mitigation specified in the standards.
- General requirements for soft edge systems
- Soft edge systems must also meet the requirements on bumps mitigation specified in the standards.
- The trampoline must be designed and constructed so that no part of the frame or legs can make contact with the user as he jumps

E. Impact evaluation

General considerations of CBA

Using available data for 2002-2003 and 2009-2010, we can estimate **that trampoline's falls account for approximately 28% of all trampoline injuries in Victoria (that is, 28% of 11.857) or approximately 3,300 attendances to the emergency department and hospitalizations during the period 2002-2003 to 2009-2010**.

The Injury Surveillance Unit of Queensland reported that, in the period between 1998 and 1999, there were **668 children injured by falls**, who were treated in the Queensland emergency departments. Of all the attendances to the emergency areas, 41% of care derived from falls from the trampoline to the ground or bumps against trampoline pieces. The most common injuries were fractures. The research center and risk management of New South Wales indicated that, **for the period between 2002 and 2008, there were more than 3,600 injuries associated with trampolines**.

The Consumer Product Safety Commission (CPSC) in the United States has recorded **11 deaths due to the trampoline use in the period 1999-2000, where six of the dead were in the age range of 12-19 years old.** The most frequent causes of death were falls from the trampoline, followed by neck fractures.

- ***Baseline scenario (maintaining the status quo)***

It is based on the industry current practice, the voluntary compliance with the Australian Standard and the current knowledge of consumers on the trampolines safety subject.

1. Costs and Benefits to Consumers

The status quo will result in the current level of risk faced by consumers and the continuation of the current level of child injuries caused by falls and impacts against the trampoline unprotected parts, such as the frame and the spring system. In

addition, children's injuries have a financial impact on the caregivers, as they will have to face the medical costs that are not covered by public or private health institutions. Also, it could happen that these people have to miss work to care for the injured children. It is expected that, when a child suffers a serious injury, the caregiver could use up his days for vacations and completely quit his income to care for their children. While this scenario creates a direct cost for caregivers, it also generates an indirect cost to the community in terms of productivity loss. There is also an emotional cost implicit in child injuries in terms of the pain and suffering that they experience, and the stress and anxiety experienced by caregivers.

Domestic trampolines encourage outdoor activity and, used with caution and with the appropriate management of the injury risk, they can improve children's health and welfare. In an environment where injuries occur frequently, consumers may perceive trampolines as dangerous and they could avoid using them, discarding such a healthy activity for children.

Moreover, **maintaining the status quo provides some benefits to consumers as they will not face higher prices due to regulation**. Often, **the regulation increases costs for providers** (such as the costs related to products improvement, products testing and the maintenance of compliance records) and such costs are passed on to consumers through higher prices. Regulation can also reduce the products range if suppliers choose not to comply with the regulations and leave the industry. Maintaining the status quo means that the current range of products and prices will not be affected by the regulation.

2. Costs and Benefits to Government

Medical expenses due to children's injuries caused by falls and blows to unprotected parts of the trampoline, such as the frame and spring system, represent the most significant cost. These costs are difficult to estimate due to the difference in the injuries seriousness as well as in their treatment. The injury can range from a sprained ankle to more serious injuries in the ribs, facial fractures and injuries in the spine and head. Similarly, the injuries treatment can vary in years of medical care and costs.

As it was previously mentioned, the trampoline promotes physical activity, which generates health-related benefits. If the use of the trampolines is perceived as dangerous, parents can prevent their children from participating in this activity, resulting in a more sedentary or inactive lifestyle for children. This lifestyle has been related to obesity, which at the same time is associated with poor health and increased public health costs. In the United States, a study on the obesity and inactivity economic costs found that the direct costs of physical inactivity account for approximately 2.4% of the spending on health care in this country. A similar study in Canada found that 2.5% of the total direct cost of health care was attributed to physical inactivity.

By maintaining the status quo, the main benefit for the government is that there would be an additional regulation to develop and implement.

- ***Government regulatory proposal on safety standards and consumers' education*.**

1. Costs and Benefits to Consumers

If the trampolines supply is regulated and the industry is forced to comply with key sections of the Australian Standard, which focus on the requirements to address risks, industry participants will comply with the regulation, thus incurring higher costs, or they will decide that they are unable to compete and they will leave the industry. If providers incur higher costs, such costs are expected to be passed on to consumers through higher prices. Furthermore, if providers leave the industry, the range of products would decrease and the supply could drop below the demand, resulting in even higher prices.

It is expected that most industry participants improve their products to ensure the compliance with the safety standard proposal. The industry has provided advice to the Australian Competition and Consumer Commission (ACCC), which suggests that the most expensive trampolines are closer to meet the Australian Standard, so they will require fewer adjustments or improvements of their products to ensure this standard compliance. **Several industry participants stated that trampolines prices would rise between 15 and 25%** in order to meet the requirements of the Australian Standard.

It is expected that the most important benefit for the government regulation consumers is the reduction in the number of children injured by blows to unprotected parts of the trampoline, such as the frame and the spring system. Also, a reduction in the number of children injured will decrease the caregiver or legal guardian absences at work. In addition, injuries related to emotional trauma and stress for both, children and their caregivers will fall once fall the injuries rates are reduced.

There is the possibility that, after the regulation, trampolines use and supply decrease (due to increased prices), which could result in a reduction in physical activity and an increased risk of obesity. It is also likely that the use the device increases in the long-term as the rates and the seriousness of injuries decline as a result of the regulation and on the trampoline perception, as it is seen as a less risky activity
.
ACCC has been unable to identify deaths in Australia caused by impacts on the trampoline's unprotected parts, but there is no reason to suppose that this will not change in the future. It is very likely that a mandatory safety standard based on the existing Australian Standard reduces the risk of death and injury. There have been various estimates of the life value in dollars, both abroad and in Australian experts' investigations. Although the range of the estimates in the studies is very broad, we can say that all experts attribute a significant quantity in dollars to the value of a human life. So, **based on the standards of "The value of life and health for public policy,"[1] it was estimated that the value of a lost life is between $3.3 million to $6.6 million.**

The OBPR also emphasizes that the Australian Institute of Health and Welfare (AIHW) has published figures for most diseases and injuries. The injuries can occur due to impact with the trampoline's unprotected parts, such as the frame or spring system, can range from

[1] Abelson, P., 2003, *The Value of Life and Health for Public Policy*, The Economic Record, Vol. 9, June 2003, p. 2–13.

bruises to broken limbs or serious head injuries and paraplegia. The AIHW provides figures for unintentional injuries, such as fractures (0.153) and intracranial injury (0.359).

From 2007 to 2011 the value of a statistical year of life increased, using information on the IPC of the ABS as the OBPR recommended, to reach a value of $170, 576[2] (2011). VISU provided information about injuries such as fractures, sprains, open wounds and intracranial injuries and these figures have been extrapolated to reach a national estimate of injuries caused by falls on the trampoline (not falls from the trampoline). Using data provided by VISU, the estimated value that society grants to the reduction of the injuries risk caused by falls on the trampoline frame and on the spring system is approximately $30 million for one year or $150 million dollars (2011) for a period of five years. This figure does not include the value of savings by a decrease in medical costs and the fall in the caregiver or guardian absenteeism in the workplace.

2. Costs and Benefits Estimate for the Industry

The government regulation often results in increased costs for industry. Suppliers are expected to incur costs to ensure that their products meet the mandatory safety standard proposal. In addition, suppliers are expected to face compliance costs due to products testing and record-keeping costs to show that the standard has been met. It is also expected that most of these costs are passed on to consumers through higher prices, although some costs may be absorbed by businesses. As it was previously mentioned **it is expected that trampolines prices increase approximately 15-25%, and a significant proportion of this increase will be related to the costs increase faced by suppliers.**

In addition, some providers may choose not to meet the requirements of the proposed safety standard and leave the industry, this is, **the regulation has an impact on competition since it changes the structure of the market by limiting the entry to suppliers**, turning the market in a more concentrated one. Many low cost trampolines have a frame and a small spring system and there are some that do not even have them, and it is possible that those that have a pad do not meet the impact mitigation requirements demanded by the safety standard proposal. Thus, these suppliers are expected to incur the highest costs increase to ensure compliance with the standard, which could prevent them from staying in the market.

Those who remain in the industry will benefit from the regulatory certainty. All suppliers will trade under the assurance that their competitors' products will have similar safety features. At the same time, a reduction in the number of injuries could result in an increase in demand, leading to increased sales as long as consumers change their minds on their trampoline perception as a dangerous device.

3. Costs and Benefits to the Government

For the government, the introduction of a mandatory safety standard would result in costs from the development, administration and enforcement of this rule. Specific costs for a period of five years are estimated in Table 1 and they include:

- The development and a revision of the mandatory safety standard proposal ($ 70,000 Australian dollars (AUD))

[2] Australian Dollars of 2011

- Australian Standard participation in the revision (AUD $ 10,000)
- Compliance with the mandatory safety standard proposal through market monitoring and enforcement/compliance activities (an average of AUD $57,000 per year). Compliance and enforcement activities that include market surveillance, market research and possible legal actions for non-compliance, and
- Industry education campaigns to increase safety standards knowledge among suppliers (AUD $ 26,000). The consumer education costs are not included, since these costs are expected to be applied regardless of the alternative chosen.

Table 1: Government costs summary due to the trampolines regulation

Activity	Cost (AUD $Nominal)	Cost for a period of 5 years (AUD $Nominal)
Development of safety standards and revision	$70,000	$70,000
Participation in the Australian Standard revision	$10,000	$10,000
Market supervision and surveys (cost per year)	$57,000	$285,000
Provide an educational campaign, including the development and distribution of a guide for the provider and, if necessary, an educational campaign for the provider that could include a seminar (Extended costs for a period of 5 years)		$26,000
Total		*$391,000*

The benefit of the regulation will be a decrease in the number of injuries and suffering associated with these injuries, savings in medical costs and reduced absenteeism in the workplace.

It is estimated that consumer costs associated with regulation will be between AUD$45 and AUD$75 million, with costs to the government of approximately AUD$391,000, for a five years period.

F. Choosing the best regulatory alternative

The regulatory proposal had only two possible ways, regulate or not regulate. Then, after the preliminary analysis of the costs and benefits, it was determined that **the economic benefits outweigh safety standards by a wide margin to the costs of implementing the standard as well as the costs of compliance.**

G. References

Abelson, P., (June 2003) "*The Value of Life and Health for Public Policy"*, The Economic Record, Vol. 9, pp. 2–13.

Australian Competition and Consumer Commission, (2012). "*Draft Regulation Impact Statement: Domestic trampolines*", Office of Best Practice Regulation Reference: 11718.

H. Glossary

- ABS: Australian Bureau of Statistics
- AIHW: Australian Institute of Health and Welfare
- NSW PSC: New South Wales Products Safety Commission

- ACCC: Australian Competition and Consumer Commission
- CPSC: Consumer Products Safety Commission
- VISU: Victoria Injury Surveillance Unit
- OBPR: Office of Best Practice Regulation
- AUD: Australian Dollars

I. Problems the regulator faced when evaluating the regulatory impact.

The most important challenges in the regulatory process were:

- Since we have a proposal for social regulation, the way to quantify costs and benefits of the proposal is a major challenge, which requires indirect methods for impact assessment and require monetize the results. Therefore, indirect methods require resources and trained personnel.

- The proposal had challenges about consensus between stakeholders, because trampolines industry argued that carrying out the proposed regulations would significantly raise costs, by reducing profit margins. Given this situation, it had to resort to international experience and other regulatory frameworks, along with cost-benefit analysis, in order to convince the industry that the proposal far exceeded the costs, so that competition in the industry is not going to affected by the new safety standards.

Matter of regulation	**"Cigarette Ignition Propensity Regulations And Regulations Amending The Tobacco Reporting Regulations" (Health Canada)**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology (**X**) Cost of illness method (**X**) VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify

Decision criteria	(**X**) Sensitivity analysis ( ) Immediate Rate of Return (**X**) Other, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal Rate of Return

Case 2. Cigarette Ignition Propensity Regulations And Regulations Amending The Tobacco Reporting Regulations (Health Canada)

A. Introduction

The Department of health in Canada proposed a regulation to deal with the problem of public health that result from the fires caused by cigarettes, so this study case assessed the regulatory proposal which implies issuing the Regulation of the propensity of fire by cigarettes and a change to the Regulation of Tobacco Reports.

The Canadian Department of Health proposes that manufactured cigarettes should have a lower probability of ignition, such as upholstered furniture, mattresses and bedclothes, in order to reduce deaths and injuries associated with these fires.

B. Identification of the problem

The fires started by cigarettes materials are usually caused by throwing or leaving cigarette materials either smoking in bed or while people is under the influence of alcohol, illegal drugs or medical treatment. When a cigarette is lit and it has contact with flammable products, such as mattresses, bedclothes or upholstered furniture, it can start a slow combustion process that can continue undetected for some time before bursting into flames. The smoke from burning materials can cause temporary blackouts, increasing the chance of suffering serious injury or even death. Given these facts, it is not surprising that residential fires have a mortality rate much higher than fires caused by other sources.

In Canada, the smokers' wastes are the main cause of fires in residential areas. From 1995-1999, the **Canadian Association of Chief Firefighters reported that at least 14,030 fires were started by the smokers' materials (including cigars, cigarettes and pipes). These fires killed 356 people, 1,615 were injured also the cost of property damage was higher than $200 million Canadian dollars (CAD).** The victims of these fires often are the most vulnerable within society: children, elder people and the economically poor.

After 20 years of research, the Department of Health believes it is possible to reduce the cigarettes ignition propensity by altering certain design characteristics of manufactured cigarettes. The design changes to reduce the heat intensity generated could include decreasing the circumference, the tobacco density and the paper porosity. The decrease in the tobacco density and in the cigarette circumference could affect the available amount of fuel (tobacco); decreasing the paper porosity would limit the oxygen flow to the fuel. In July, 2000 an American cigarettes producer introduce to the market a version of the product that reduces the ignition probability. Nevertheless there is not a legislation that makes mandatory for cigarettes producers to include this type of technology in their products

The identified problem shows the necessity of a government intervention in order to overcome the **government failure** that arises from the lack of regulation that provides mandatory legislation to include in the production process of cigarettes the appropriate technology that reduces the risk of ignition.

C. Objectives of the intervention

In this sense, The Canadian Health Department has the main objective of the best possible health state of Canadian population. The last includes avoiding negative effects of residential fires; this is reducing deaths, injuries and property damage resulting from fires caused by manufactured cigarettes. So, the main objective of a government intervention is to decrease the number of residential fires by reducing the risk of ignition of Tabaco products, mainly of cigarettes.

D. Regulatory alternatives

A number of alternatives were considered in the analysis to determine the need and feasibility of the ignition propensity reduction of tobacco products in the following way:

- ***Baseline scenario (not issuing regulation).***

This option implies the no intervention of the Authority which means that the identified problem continue its occurrence. Under this scheme there is no possibility to have control over the standards of ignition for tobacco products. The last implies that residential fires will continue as well as the economic and human losses that these arise.

- ***Technical standards****.*

The Department of Health proposed the issuance of standards of production to reduce the propensity of ignition according to the established in the ***ASTM E2187-02b standard***. The Authority considered different stringency standards: a regulation of 0% percent of total consumption of three layers of filter paper, a very strict standard; a less strict standard, which is 50% percent of full burns in ten layers of filter paper, and finally a standard of 25% percent of full burns in ten layers of filter paper.

Thus, this alternative requires that, from October 1st, 2005, all cigarettes manufactured or imported in Canada must burn its entire length to no more than 25% of the time, based on 40 replicate tests with cigars with 10 layers of Whatman No. 2 filter paper, as indicated in the *ASTM E2187-02b*. This standard prescribes a goal that allows manufacturers the freedom to use the manufacturing process or technical design of their choice to do so. All cigarettes manufactured in Canada must comply with the standard of ignition propensity, including the cigarettes manufactured for export.

Additionally, in response to a concern raised by the industry regarding the possibility of a toxicity increase, the proposed amendments to Tobacco Regulation required manufacturers and importers to carry out annual toxicity tests to the cigarette brands sold in Canada. Manufacturers and importers are required to submit the results of these tests to the Department of Health, on an annual basis.

E. Impact evaluation

General considerations of the CBA

The purpose of the intervention is reducing deaths, injuries and property damage resulting from fires caused by manufactured cigarettes. Therefore, the direct benefit of the regulatory proposals would be equal to the monetized value of the avoided damage effects on health.

The first step in the assessment of these benefits is to estimate the situation in the absence of regulation, which is the baseline scenario. To this end, this analysis uses the annual reports of the Canadian Council of Fire Commissioners and the data of the states of Alberta and Ontario.

The Canadian Council of Fire Commissioners publishes annual reports that provide national data on losses caused by fires. These reports show what smokers' articles (including cigarettes, cigars and pipes, as well as lighters and matches used in conjunction with smoking) caused, on average, more than **3,200 fires per year between 1992 and 2000, which resulted in an annual average of 75 deaths, 349 injured people, and CAD$ 44.7 million in nationwide property damage during this period. The data also show that firefighters represent 22 % of the affected population, while civilians represent 78%.** These percentages are used later in the analysis to separate firefighters' injuries from civilians' injuries in order to assess the potential benefits of the regulation proposal.

Alberta is the only province that registers cigarettes as an incandescent source. This is why this analysis uses loss by fire data from Alberta, to adjust national loss by fire data, exclusively attributable to cigarettes. This adjustment shows that the cigarettes ignition accounts for 75% of fires, 82% of deaths, 76% of injuries and 73% of property damage. Furthermore, not all cigarettes are manufactured in Canada, the Canadian sales data of 2002 indicated that about 86% of all the sold cigarettes were manufactured, 14% were tobacco sticks or hand-rolled cigarettes.

- ***Baseline scenario (not issuing regulation).***

Now, it is possible to set the scenario without regulation based on this data, which involves identifying the percentages and thus, the number of deaths, injured people and property damage. Thus, **manufactured cigarettes would cause about (0.75 * 0.86 * 3200)[3] = 2.064 fires per year caused by cigarettes in Canada, resulting in an average of:**

- **(0.82 * 0.86 * 75)[4] = 53 deaths,**
- **(0.76 * 0.86 * 349)[5] = 228 injured people (51 firefighters, 177 civilians) and**
- **(0.73 * 0.86 * $ 44.7 million)[6] = $ 28.06 million in property damage.**

[3] This is given by: 75% of the fires were caused by the cigarettes ignition, 86% of all manufactured cigarettes were sold and 3,200 is the total number of fires per year.
[4] This is given by: 82% of deaths are caused by fire, 76% of injuries are caused by the cigarettes ignition and 75 is the total number of fatally injured per year.
[5] This is given by: 76% of injuries are caused by cigarettes ignition, 86% of all manufactured cigarettes were sold and 349 is the total number of injured people per year.
[6] This is given by: 73% of property damages are caused by fire, 86% of all manufactured cigarettes were sold and there was a loss of CAD$ 44.7 million of property damages at national level per year.

National data on the nature and severity of civilian injuries related to the fires by cigarettes are limited. For this reason, national data are complemented with injuries data from the Bureau of Ontario, which have information on the nature and severity of the injuries suffered as a result of fires caused by smokers' incandescent material. Table 1 summarizes the results of an assessment of injuries data in Ontario for 1995.

Nature and severity of the injury	Percentage of total injuries
Suffocation / Respiratory Condition – Mild	27.6%
Suffocation / Respiratory Condition – Serious	17.7%
Burns or scalds – Mild	13.8%
Burns or scalds – Serious	11.4%
Others – Mild	20.1%
Others – Serious	9.4%
Total	*100%*
Notes: The category "Others" includes injuries identified as "unknown." To characterize the global distribution of injuries, the injuries of unknown severity are assigned to the category of mild or severe, according to the severity of other reported injuries of the same type.	

Source: Analysis of injury data from the Firefighters' Chiefs Bureau, Ontario

The data show that **the most common injuries caused by fires started by smokers' incandescent materials in Ontario are suffocation or respiratory conditions (45.3%) and burns or scalds (25.2%). Slightly less than 40% of the reported injuries are identified as serious.** The analysis applies this information to characterize the probable distribution of the injuries attributable to fires caused by manufactured cigarettes.

- ***Technical Standard***

1. Costs

To analyze the impact of the regulatory proposal on the tobacco industry a reference model was developed to analyze the costs structure for a representative cigarettes manufacturer. The cost analysis was conducted in two parts: on the one hand the costs and impacts were estimated based on the costs model developed by the Department of Health; on the other hand a survey to the affected industry was made.
Both the model and the estimates based on surveys include the following costs:

- Manufacturing, quality control and other costs of compliance with the standard trend of ignition;
- Toxicity testing and reporting required by the regulatory proposal;
- Additional evidence of potential emissions and printing costs to meet regulatory reporting, and
- Expenses for research and development (R&D).

The results of this model show that **the total production costs (that is, before taxes and profits) for a representative cigarettes manufacturer is about $ 5.70 per cigarettes pack.**

For the disclosure survey in the industry, questionnaires were sent to all known cigarette manufacturers and importers, as well as a sample of other potentially affected parties, including retailers, distributors, producers and unions. To make the response easier, a summary of the planned regulations was included, and the questionnaires were adapted for each sector, for example, the questionnaire for manufacturers included a base

structure estimated for a representative manufacturer of cigarettes with examples of possible changes in this costs structure as a result of the standards.

The estimate stated that the **cost of compliance was CAD$ 0.126 per pack, while the survey estimated CAD$ 0.257 per pack, this results in annual costs of $ 26 million and $ 53 million, respectively.**

2. Benefits

a. Monetization of Life (VSL)

The analysis uses the approach of the **Value of Statistical Life (VSL)** in order to assign an economic value to the deaths reduction. This approach estimates a profit of $ 5.8 million per life saved.

b. Monetization of Illness (COI)

The **Cost of Illness (COI)** is an approach used to reduce the estimated value of the injuries resulting from the regulatory proposal. This approach includes direct medical costs, such as emergency transportation and care, hospitalization, medication and doctor visits. However, the approach does not calculate the indirect costs, such as an individual's willingness to pay to avoid a health effect or the productivity loss, nor does it attempt to assess the intangible costs such as pain and suffering. The COI is considered as a lower bound of the economic assessment of the illness or injury.

According to the previous, estimates of the cost of treating injuries caused by fires are presented in Table 1, based on a 1993 study on the social costs of fires caused by cigarettes in United States (Miller et al., 1993).

Table 1: COI Values, civilians' injuries in 2002 expressed in dollars

Severity of the injury	Injury category		
	Anoxia	Burns	Others
Severe – Hospitalization	7,777	78,738	21,963
Severe - No hospitalization	1,072	1,072	791
Mild	151	151	151

Firefighters are less likely than civilians to suffer serious burns or other injuries caused by fire, since they face the fire alarm and well trained and protected. The United States study estimated a cost of $ 1.679 for nonfatal injuries in firefighters. This amount is included in the health care costs.

c. Potential benefits (reduction scenarios)

The benefit of the regulatory proposal is the reduction of the human and economic losses related to fire as a result of compliance with the ignition propensity regulation. Two scenarios are used to calculate this potential benefit:

- **Scenario 1:** reduction of 68% in fires caused by manufactured cigarettes; this is regarded as the best scenario
- **Scenario 2:** reduction of 34% in fires caused by manufactured cigarettes.

Was previously determined that the cost of regulatory compliance was $0.126 Canadian dollars per box, while the survey were estimated at $0.257 Canadian dollars per box of cigarettes, this results in **annual costs of $26 million and $53 million respectively**. On the other hand, the total expected benefits from the regulatory proposal are:

Table 2: Expected benefits from regulatory proposal

Reduction Scenario	Reduced Fatalities	Reduced Injuries	Reduced Property Damage	Total Benefits
Scenario 1	208.8 million	0.2 million	19. 1 million	228.1 million
Scenario 2	104.4 million	0.1 million	9.6 million	114.1 million

F. Choosing the best regulatory alternative

The following table shows the net benefits of regulation, which is the difference between total costs and benefits of the proposed regulation:

Table 3: Annual benefits from regulation

Reduction scenario	Total benefits	Estimated compliance costs	Compliance cost survey
Scenario 1	$228.1 millions	$26 millions	$53 millions
	Net Benefits	*$202.1 millions*	*$175.1 millions*
Scenario 1	$114.1 millions	$26 millions	$53 millions
	Net Benefits	*$88.1 millions*	*$61.1 millions*

In both scenarios the **net benefits are positive**, which means that is socially efficient to issue the regulatory proposal. This means that the benefits of implementing the regulation outweigh the expected costs of the regulation by a factor of 2 or more.

G. Final remarks

The main purpose of the regulation was to reduce the number of deaths and injuries resulting from fires started by cigarettes, therefore, the methods used, VSL and COI, showed controversy because these methods estimate the value of life in money. So, find acceptance in the industry and other political actors to the use such methods was the most relevant difficulties. However, the challenge was overcome because policymakers in Canada due to international experience to support the use of the methods in similar situations.

H. References

Health Canada, Regulatory Impact Analysis Statement for the proposed Cigarette Ignition Propensity Regulations and proposed Regulations amending the Tobacco Reporting Regulations. Can be consulted on the following link:
http://www.hc-sc.gc.ca/hc-ps/pubs/tobac-tabac/rias-reir/index-eng.php#potential
Health Canada, Tobacco use statistics. Can be consulted on the following link:
http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/index-eng.php

Matter of regulation	**"Emission Standard Particulate Matter for Artifacts which Burn or can Combust Wood and Wood Derivatives" (D.S. N° 39, De 2012, Ministry of Environment)**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology (**X**) Cost of illness method (**X**) VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	(**X**) Sensitivity analysis ( ) Immediate Rate of Return ( ) Other, specify:	( ) Monte Carlo method ( ) Internal Rate of Return

Case 3. Emission Standard Particulate Matter for Artifacts which Burn or can Combust Wood and Wood Derivatives. (D.S. N° 39, De 2012, Ministry of Environment)

A. Identification of the problem

Over decades, many cities in the middle-southern part of Chile have suffered air quality problems related to particulate matter. Authorities have used different mechanisms to reduce the effects on health caused by high environmental concentrations of such pollutant. In this context, in 1998 a regulation came into force to control Particulate matter 10 (PM10), but it was until January 1st, 2012, that the regulation of fine particulate matter (PM2.5) came into effect.

Several studies agree with giving great responsibility of bad air quality to the intensive use of wood as fuel for heating and cooking purposes at residential level. According to estimates, cities like Rancagua (214,000 inhabitants), Temuco (340,000 inhabitants) and Coyhaique (50,000 inhabitants) have a significant percentage of the total emission from this factor, reaching values of 45%, 97% and 94%, respectively (DICTUC, 2008; EnviroModeling Ltda, 2009; Mardones, 2010).

The great volume of residential emissions related to wood consumption is caused by the presence of (i) a great number of individual contribution sources, which makes it difficult to control and measure; (ii) low wood prices, which cause no new incentives to change to another fuel with less emission ; (iii) heaters with low efficiency and high level of emissions; (iv) bad wood combustion, as a result of using residential appliances; (v) the use of highly damp wood and (vi) houses' low thermal insulation. Due to these reasons, implementation to reduce residential emission must combine economic, social and cultural factors in order to achieve its goal.

One of these measures is promoting improvement on technological equipment used for heating. It is a goal of the "regulation on emissions of breathable particulate matter for wood combustion residential appliances," driven by the Chilean Ministry of Environment. This regulation has a nationwide implication and limits the emissions of the new equipment or the ones that are for sale, but does not apply to the current home equipment available. They are arranged in three groups, according to power, as shown in **Table 1**.

Table 1. Regulation of new equipment according to power

Equipment	Power	Maximum Emission
Small	< 8 kW	2.5 g/h
Medium-Sized	8 kW to 14 kW	3.5 g/h
Large	> 14 kW	4.5 g/h

Source: Regulation on emissions of breathable particulate matter for wood combustion residential appliances.

B. Objectives of the intervention

The target of the regulation on emissions of breathable particulate matter of wood combustion for residential appliances is technological improvement of equipment, by entering emission factors considerably lower. This increase in technology also solves

some of the problems caused by poor operation equipment (less options to regulate the circulation) and humidity (the gas burning time is longer).

The purpose of the rule is to protect the health of the people, by controlling breathable particulate emissions produced by residential use appliances for combustion of wood and other biomass fuels that are manufactured or imported into the country.

C. Regulatory alternatives

In the absence of specific regulations on the quality of the wood, in Chile this resource is not considered as fuel, the control of pollution from burning wood is based on controlling the variables involved in the combustion process; for example, equipment that enable combustion and operation thereof.

The rule is to set the maximum heating emission factor to 2.5 g/h of PM and with an efficiency of 70% for all new equipment that were sold from the year 2012.

The economic evaluation on emission regulation of heaters was made through an air quality costs-benefit analysis (CBA), widely used in literature for social evaluation projects. First of all, an analysis per heater is made, this is, benefits and costs for a unit of improved equipment for each city, in order to use national data from projected sales with the purpose of determining the nationwide evaluation.

The analysis compares the costs and benefits associated with changing existing technologies to more efficient combustion technologies by analyzing a unit, considering features such as moisture from the wood, emission factor of the equipment used and operating quality (manipulation) of the equipment.

On average, it is estimated that emissions unit due to humidity increases from about twice the baseline emissions, and poor operation up to 5 times the emission factor (EF) in ideal conditions. With these assumptions, it is possible to isolate the analysis of each fuel-wood problem, because depending on the type of heater parts, the influence is different.

$$EF_{Total} = EF_{Base} + \Delta EF_{Humidity} + \Delta EF_{operation}$$

The analysis considered the full range of feasible replacement equipment that met the standards, evaluating (for simplicity of analysis) only one kind of equipment that meet the basic features.

D. Impact evaluation

1. Cost analysis

For the evaluation of the costs it is important to know the type of equipment prevalent in homes and, from the social point of view, it is also important to determine whether if there are significant differences between socioeconomic strata.

The cost associated with the rules is attributed to the equipment purchased by consumer, who must pay an additional amount equal to the difference between the machine base 5 and 500 USD for the one of 2.5 g/h (Environment Consultants 2007). The following table

details the values mentioned by socioeconomic strata. Installation cost is assumed constant in both scenarios, so does not influence the incremental cost analysis.

Table 2. Equipment cost, base cost and incremental cost by social-economic stratum (USD/equipment).

Social Economic Level	Equipment Cost (USD/equipment)	Incremental Cost (USD/equipment)
Low	270	310
Medium	320	330
High	370	400

Source: Self-made study on Ambiente Consultores, 2007 basis.

The measure involves higher costs for lower socioeconomic levels because, on average, households with those characteristics acquire equipment with fewer characteristics, than those of higher income levels (difference between the "Low" and "High" of 100 USD). This fact supports the incorporation of a state subsidy for replacement the equipment.

The methodology used to estimate the change in the concentration of $MP_{2,5}$ uses the assumption that can be approximated by emission-concentration factors used by DICTUC in the evaluation of the primary quality standard $MP_{2,5}$. This implies a linear relationship between the emissions of a pollutant and the concentration that it produced in the air by the following equation.

$$ECF_i^t = \left(\frac{\partial C_i^t}{\partial E^i}\right)^{-1} \approx \frac{E_i^t}{C_i^t}$$

Where:

ECF_i^t = Emission concentration factor in the area í in the year *t*
C_i^t = Environment concentration corresponding to the emitted pollutant in the area í in the year *t*
E_i^t = Emission of pollutant in the area í in the year *t*

In simple terms, the ECF (emission-concentration factor) represents the tons required to reduce (output) or decrease (increase) to 1 ug/m3 concentration MP2, 5 at its annual average.

2. Benefit analysis

The benefits are evaluated according to the reduction of effects on population health and on firewood consumption by users of the equipment.

a. Health Benefits

The health benefits consider reductions in diseases caused by air pollution, including cases of mortality, morbidity, lost productivity and days of restricted activity. The economic valuation of health effects can be estimated in the following ways:

- Through cost measures including treatment of illness and lost productivity for not worked days (COI method, for its acronym in English "Cost of illness").

- Through measuring the willingness to pay of individuals, in order to reduce their health risks, including levels valued by the COI method over the welfare loss that involves being sick ("Willingness to pay").

b. Benefits of reducing firewood consumption

Changing to a heater with better features leads to a saving on fuel wood consumption (∆ consumption) because of its greater thermal efficiency in heat generation. This means a saving in fuel consumption. It is used in the study a value of 0.1 USD / kg of firewood.

The benefit for fuel use, which is assimilated by the consumer of wood, is calculated according to the following Equation. This calculation implicitly assumes that the user energy demand remains constant, i.e. does not need more heat than the one required in the base case. Therefore, the difference in consumption is calculated by using the stoves efficiencies (η) and the consumption of the base case (∆ $Cons_{Base}$).

Equation:

$$Ben_{consumer}\left(\frac{USD}{year}\right) = Wood\ Price\ \left(\frac{USD}{kg}\right) * \Delta Consumption\left(\frac{kg}{year}\right)$$

$$\Delta Consumption = \left(1 - \frac{\eta_{2,5g/h}}{\eta_{Base}}\right) * \Delta Cons_{Base}$$

We performed a sensitivity analysis to the present value (PV) of the net profit per unit and the national annual net profit by the change in three important variables in the model:

- Discount rate: The rate considered in the overall results corresponds to 6% and this analysis shows the variation of the results to variations between 0% and 12%.
- ECF: 208 ton/ug/m3 and variations between 25% (52 ton/ug/m3) and 200% (424 ton/ug/m3) that value.
- Is assumed that an exchange in equipment costs $500, which in this analysis varies between 25% (125 USD) and 200% (1000 USD).

In all graphs, the turning point is highlighted for the value used in this study and for each variable the results are plotted in a graph with the same scale in order to compare them.
As shown in the following figures, in the three sensitivity analyzes for both cases, the unit profit (for heating) and the aggregate net profit of the draft standard is positive, even with the extreme values analysis, with an unlikely occurrence.

We would highlight the sensitivity analysis for the ECF, which significantly increases the net benefit to that used for smaller values and comparatively minor changes to values greater than 208 ton/ug/m3. Moreover, it is noteworthy that this assumes other sources such as: ECF (Sanhueza, 2004) equal to 126 increases by approximately 70 MMUSD/year benefits of the standard.

Finally, we conclude that the variation in the price of heating of 2.5 g/h produces comparatively significant changes in the results

Figure 1. Present value of net profit per unit by sensitizing the discount rate (USD / equipment)

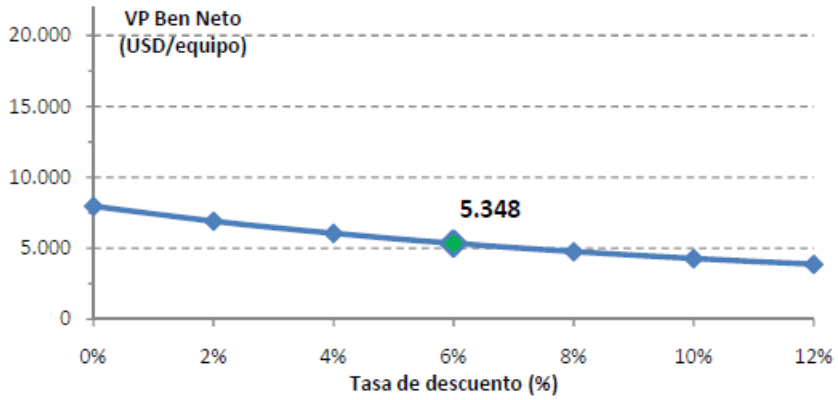


Figure 2. Present value of net profit per unit by sensitizing Concentration Emission Factor (USD / equipment)

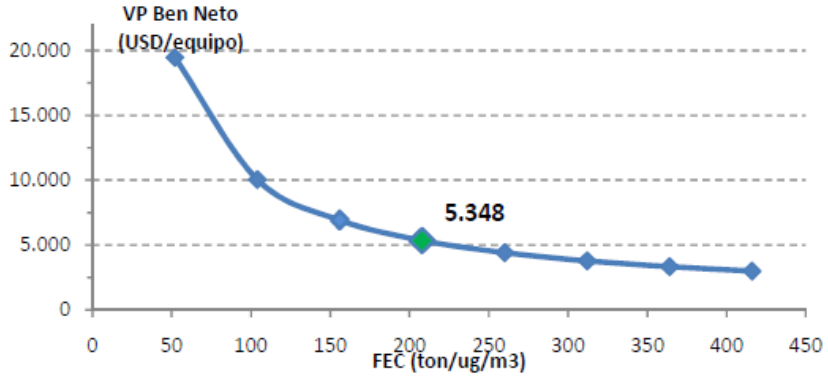


Figure 3. Present value of net profit per unit by sensitizing the cost of replacement equipment (USD / equipment)

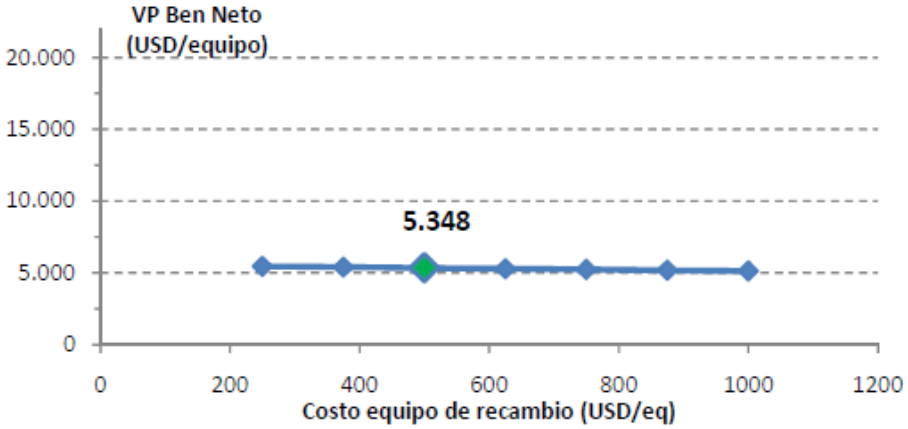


Figure 4. Annual Net Profit by sensitizing the discount rate (MUSD / year)

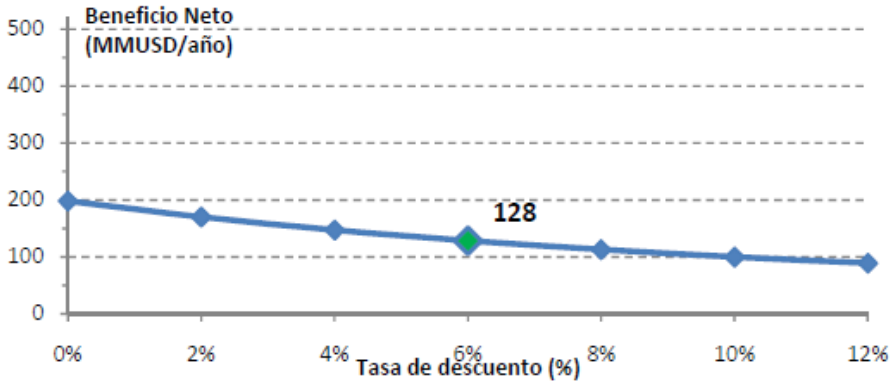


Figure 5. Annual Net Profit by sensitizing Concentration Emission Factor (MMUSD/year)

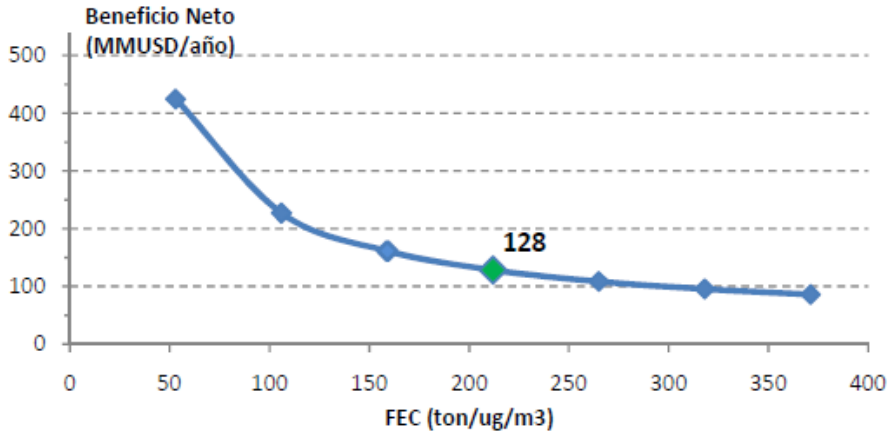
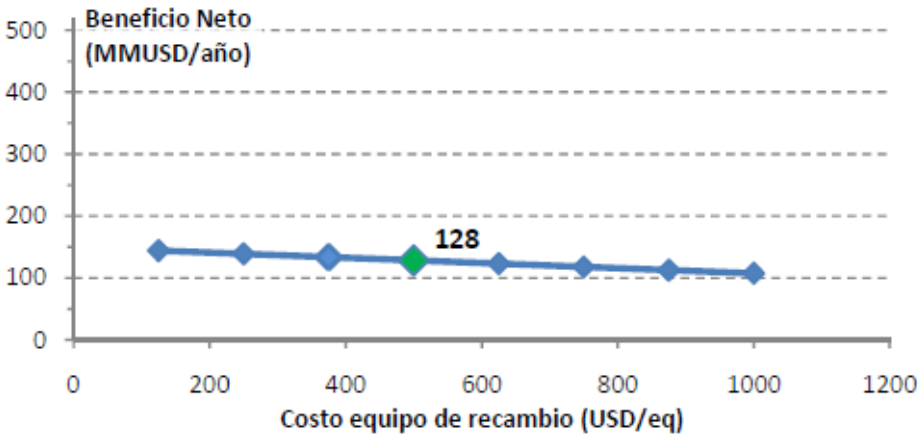


Figure 6. Annual Net Profit by sensitizing the cost of replacement equipment (MMUSD/year)



E. Choosing the best regulatory alternative

The next Table compares unitary emissions between the average equipment estimated and the 2.5 g/h one, for different socioeconomic levels.

Table 3. Average heating equipment features and 2.5 g/h equipment features, for each income level, Temuco and Padre las Casas

Socieconomic Level	Emission Factor (gr/kg-equipement)	Wood Consumption (kg/year)	Average heater annual unitary emissions (kg /equipment-year)	Heater annual emissions (kg/equipment-year)
Low	8.0	3,470	33	5
Medium	7.1	5,490	44	8
Higher	6.7	7,590	55	12

Source: Self-made study.

The difference between equipment is the reduction of emissions for each new piece of equipment. It is assumed that each house will have a heater that fulfills regulations properly, rather than equipment with worse emissions.

Using the values reported in the study, it is possible to calculate the present value of the benefits and costs for a unit of new equipment purchased by the consumer, including the values of reducing emissions, consumption, and the increase in price for the equipment (the results only apply for Temuco commune country).

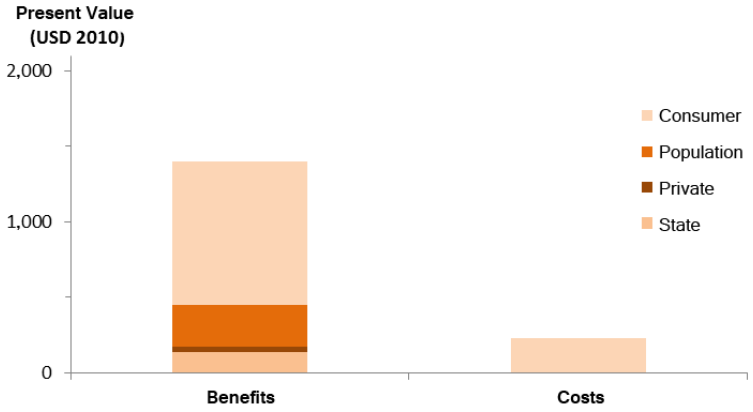
To do this, it was considered a discount rate of 6% and a period of 15 years of evaluation considering the lifespan of a heater. It is assumed that the National Health Fund receives 4%, ISAPRES (Instituciones de Salud Previsional – ISAPRE, according to its acronym in Spanish) 1%, private sector 8% and mortality 87% of the total benefits (DICTUC 2011).

Results were disintegrated by the different social agents, affected by the regulation's costs and benefits, which is shown when the State reduces the costs in the National Health Fund (Fondo Nacional de Salud – FONASA, according to its acronym in Spanish); the private sector reduces its expenses in the health insurance companies (Instituciones de Salud Previsional – ISAPRE, according to its acronym in Spanish); people reduces its medical expenses and consumers receive saving benefits when purchasing wood and in the incremental cost of a new heater (DICTUC, 2011).

Benefits from implementing this regulation strongly depend on the strength of the usage of each heater; which is seen in the annual volume of wood used for heating, at the same time, it depends on the weather of each city. Therefore, consumption of each city is taken into account for the analysis.

For example, for the Temuco case (next Figure and next Table), it is emphasized that even though the mortality cases are not assessed, the unitary net benefit of applying regulations is positive for every socioeconomic strata.

Figure 7. Current cost and benefit values, middle social-economic level, heater < 8kw, Temuco (USD/equipment)



Source: Self-made study.
Note: Chart with no death risk reduction assessment (Mortality RR) / 6% Discount rate / 15-year evaluation horizon.

Table 4. Current cost and benefit values, middle social-economic level, heater < 8kw, Temuco

Stratum	No mortality / benefit (USD/Equipment)	Mortality / benefit (USD/Equipment)	Costs (USD/Equipment)	No RR mortality B/C Rate	RR mortality B/C Rate
Low	1,040	3,414	263	4	13
Medium	1,402	4,416	229	6	19
Higher	1,721	5,235	232	7	23

Source: Self-made study
Note: Value of statistical life (VSL): 9,100 FU (Death Risk Reduction Method) / 6% Discount Rate / 15-year evaluation horizon.

Once the referred analysis is made, regulation would get USD$129 million of net benefit per year, which is completely attributed to avoid mortality cases by less PM emission and to save on fuel consumption. The next table shows the detailed results according to sectors.

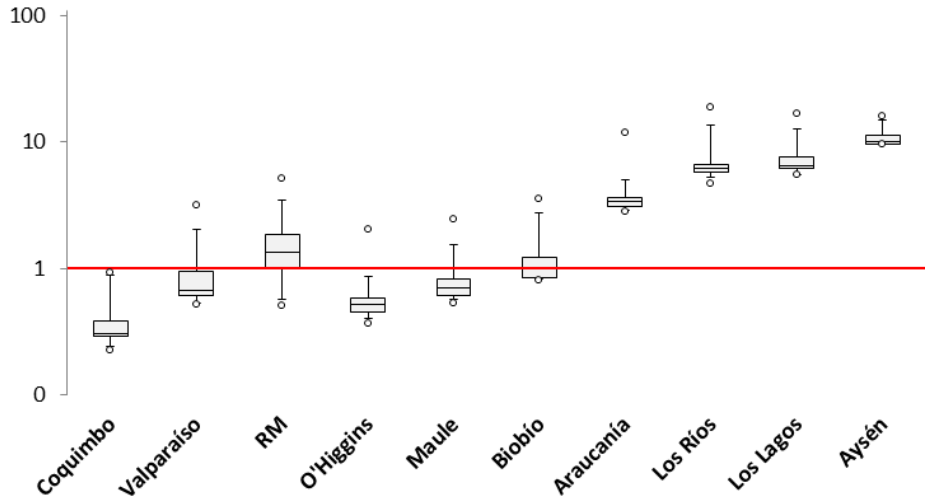
Table 5. Nationwide Cost and Benefits, year 2010 (MMUSD/year)

Sector	Benefits	Costs	Net Benefit
State	4	0	4
Private Sector	1	0	1
Population	8	0	8
Consumer	51	-20	30
Mortality	86	0	86
Total	*149*	*-20*	*129*

Source: Self-made study.
Note: Value of statistical life (VSL): 9,100 FU (Death Risk Reduction Method) / 6% Discount Rate.

The following figure shows the percentiles 5, 25, 50, 75 and 95 of the benefit-cost ratio grouped by region, for the communities that use firewood. It is observed that the indicator has values greater than 1 in most cases, with lower values in the region of Coquimbo. The two main variables that increase the benefits are the population exposed to contaminants and the relevance in emissions from wood combustion. For example, in the case of the metropolitan region (RM), their huge population is the main driver that increases the benefits, while in the case of Aysén, which is a small town, the important aspect is the relevance in emissions from wood combustion. In most cases, the 50th percentile is above the unit value, indicating that the rule is profitable for most of the communes of Chile.

Figure 8. Benefit-cost Boxplot rate for wood-consuming cities



Source: Self-made study.
Note: Value of statistical life (VSL): 9100 FU (Death Risk Reduction Method) / 6% Discount Rate / 15-year evaluation horizon.

F. Final remarks

From the revised results, in general terms, it can be concluded that the regulation for heater emission aims to decrease the harmful impacts on people's health, by imposing PM emission limits for equipment for sale.

Particularly, social-economic analysis carried out to the aforementioned regulation, allowed us to conclude the following:

The regulation will generate national net benefits, over USD$136 million/year. Most of the cities will have positive net benefits, especially in highly populated cities and/or in the ones with high emissions (middle-southern towns).

The sensibility analysis showed the presence of positive net benefits for the whole range of proposed values. This result is less sensible before the price variations of equipment replacement, but not for the ECF used. However, from the data compiled, the value used in these two variables allows to infer a conservative benefit analysis.

The present regulation impacts on wealth distribution, since the incremental cost is higher for the upper level stratum, because this stratum must acquire cutting edge heaters, so as to fulfill the regulation stipulations and its heat energy demand.

Even in low income homes, regulation incremental cost is low; the amount that should be paid supports the idea of a subsidy program given by the State, will facilitate the access to this socioeconomic stratum to acquire new equipment.

G. References

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H. Problems the regulator faced when evaluating the regulatory impact.

General Analysis Evaluation of Economic and Social Impact of the standard mean that new emission reducing heating only the component associated with "technology", discarding the item "bad operation" and "humidity" in the absence of sufficient information to ensure the percentage new technologies that reduce combustion in these topics. In this way takes a conservative analysis of the benefits of the standard.

Matter of regulation	**Regulation of emission standards for light pollution** **(D.S. N° 43, de 2013, Ministry of Environment)**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	( ) CBA ( ) Multi-criteria analysis (**X**) Equivalent annual cost	(**X**)CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method ( ) VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	(**X**) Sensitivity analysis ( ) Immediate Rate of Return ( ) Other, specify:	( ) Monte Carlo method ( ) Internal Rate of Return

Case 4. Regulation of emission standards for light pollution. (D.S. N° 43, de 2013, Ministry of Environment)

A. Identification of the problem.

The astronomical quality of the sky from the regions of Antofagasta, Atacama and Coquimbo constitutes a valuable environmental and cultural heritage internationally recognized. Its sky allows this zone to be home of several astronomical observatories, which implied a total investment of about 4,700 million dollars and it will continue to grow in the coming years. This is the reason why the regulation of emission standards for light pollution (DS [Supreme Decree] N°686/98 from Ministry of Economy) with the objective of preventing the night sky pollution, preserve the current quality of those skies and avoid its future deterioration.

Light pollution consists in the emission of luminous flux of artificial night sources towards the superior hemisphere in terms of intensities, directions, spectral ranges or unnecessary times for the realization of local activities in which luminaries are installed, such as circulation, displacement, security, etc.

This way, light pollution is every light that is not used to provide illumination for the ground or buildings. This may happen for two main reasons: whether because the light beam is not directed downwards or because light radiation is of a wave length the human eye does not perceive. There are several ways in which light can scatter throughout the line of sight, without necessarily to be a city directly visible. Therefore, the only way to control light pollution is to reduce the amount of light that escape towards the sky.

The quality of skies should not be neglected, since there are indeed alternative destinations to Chile regarding astronomical investment. As an example, in 2009 the Thirty Meter Telescope (TMT) Observatory Corporation was deciding where to set up a new infrared optical telescope, and Chile was an option. Nevertheless, it was finally built up in Hawaii. It constituted one of the main astronomical plans worldwide, since it was a US$1.3 billion dollar project, and it would have created around 140 permanent jobs. However, almost a year later, the European Extremely Large Telescope (E-ELT) was built in the same place in which the TMT was supposed to build their own telescope.

B. Objective of the intervention

The objective of this regulation is to prevent light pollution in the night skies from the regions of Antofagasta, Atacama and Coquimbo, in order to maintain the astronomical quality of those skies, through the standardization of the emission of luminous flux.

More specifically, the present regulation limits the emission of luminous flux towards the superior hemisphere from its sources. Besides, it limits certain spectral emissions from lamps, except specific applications expressly indicated.

C. Regulatory alternatives

The regulatory alternative chosen was the command and control instrument, and not an economic instrument. In fact, the following limits are established:

- Limits to luminous intensity for lamps installed in luminaries or spotlights, which are used for environmental, functional, industrial or ornamental lightning, or in luminous signs and advertisements.

- Limits to spectral radiance emission for lamps installed in luminaries or spotlights, which are used for environmental, functional, industrial or ornamental lightning.

- Limits to the emission by reflection over the driveway for the case of lamps installed in luminaries or spotlights, which are used for environmental, functional, industrial or ornamental lightning.

- Limits to the luminance emission for luminous signs and advertisements.

- Limits to the general emission for other type of light sources.

The regulation evaluates different ways of meeting the required quality for astronomical observation (i.e. schedules in which illumination of big enclosures, use of technological alternatives such as LED or SBP/SAP, electric ballasts, illumination angles of public lightning, restrictions on the use and illumination of luminous signs.

The Luminous Regulation has been successfully implemented through the Environmental Impact Evaluation System (SEIA, for its acronym in Spanish), which is applied to new projects or to modifications to existing projects. Within this system, the regulatory standards have been highly achieved; however, when replacing or updating the illumination systems, a decrease is observed in the achievements of these.

D. Impact evaluation

The methodology used in the evaluation is the Direct Search (R. Hooke and TA Jeeves 1961), which are detected replacement alternatives and choose which represents a higher net profit, also used the concept of Equivalent Annual Cost (EAC), which allows all relevant flows lead to an annual basis and make them comparable.

Then, we compared the annualized flows associated with the replacement of luminaires, i.e. with project flows, flows with base or without project situation. This difference corresponds to the total annual cost of the project, as shown in the following equation:

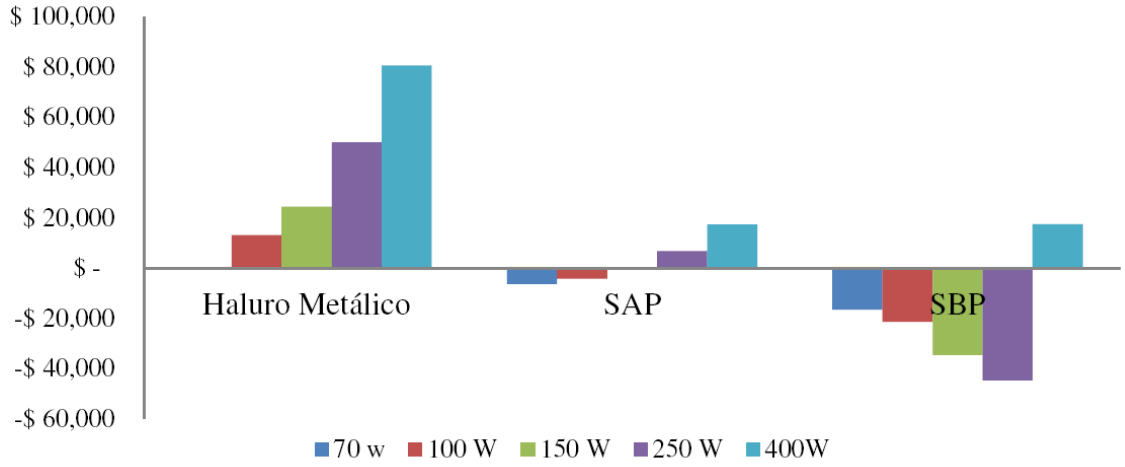
$$Total\ annual\ cost\ Project = EAC_{\ with\ project} - EAC_{\ without\ project}$$

The benefits associated with the replacement of luminaires are given by the energy savings from the replacement of fixtures and potential savings in maintenance cost due to the longer life of the new fixtures.

Now, regarding technology convenient replacement evaluate (project scenario), the main alternatives are High Pressure Sodium (SAP), Low Pressure Sodium (SBP) and Solid State Lighting (LED), while the current park consists of SAP, SBP and Metal Halide (MH).

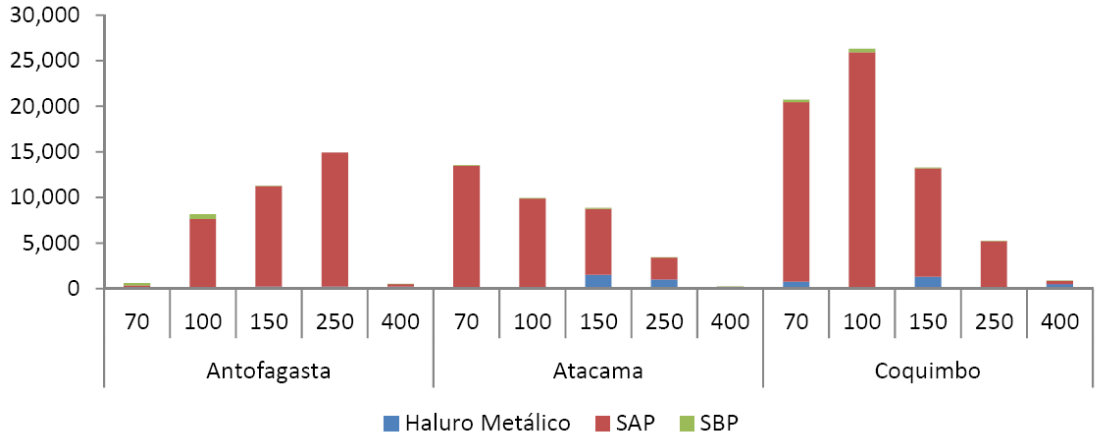
Was performed spare part analysis of luminaires unitary, that is, the benefits or costs associated with the replacement of a luminaire from the original power technology and technology to SAP and final power to install.

Figure 1. Benefit annual unit as power and technology (CLP/year)



The variability of the benefits associated with the replacement of luminaires makes the added benefit depends on the composition of the park base. The details of this park are presented in the figure below, which shows the detail of the installed power and the technologies that make up the park.

Figure 2. Park features of public luminaries, by region, technology and installed power



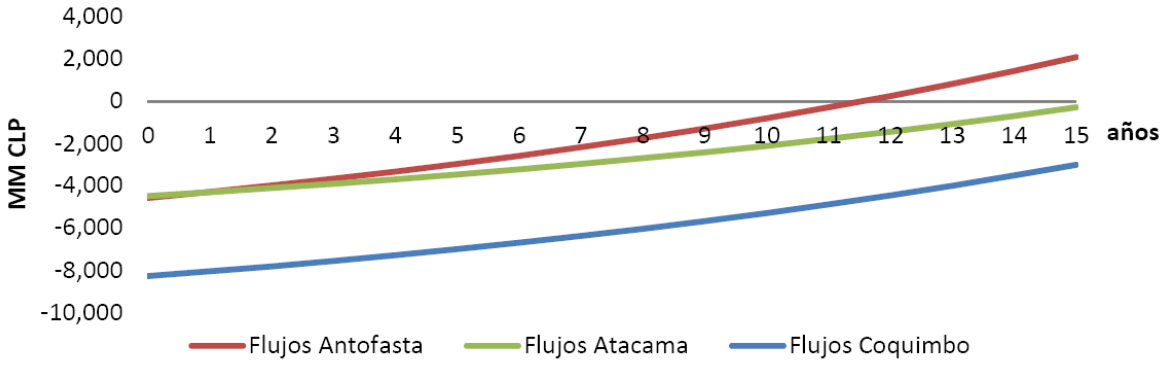
The following table presents, for each region, the net present value (NPV) of the project, the initial investment required, the annual savings resulting from lower operating and maintenance costs and net annual flow (corresponding to EAC $_{\text{with Project}}$ - EAC $_{\text{without project}}$). It is observed that there is a total net cost of 52 million pesos per year associated with the replacement of luminaires, with a net present value of 504 million pesos.

Table 1. Summary of indicators associated with the replacement of luminaires, by region[7].

	Antofagasta	Atacama	Coquimbo	Total (CLP)	Total (MM USD)*
Net Present Value ($)	870	-119	-1.255	-504	-1,0
Inversion ($)	4.582	4.489	8.288	17.359	36,2
Annual savings ($/year)	561	450	724	1.735	3,6
Net annual flow ($/year)	90	-12	-129	-52	-0,1

The following figure shows in detail the flows associated with the replacement of luminaires for all the years considered in the evaluation, where the year zero of the graph shows the negative flow associated with the investment, to be "amortized" with operating cost savings and maintenance over the years. Only in the region of Antofagasta replacement of the lights gives a positive net benefit, in which the investment is recovered in 11 years.

Figure 3. Inversion and annual savings



[7] Exchange rate of 479,63 pesos/ dollar, the August 24, 2012.

Figure 4. Luminaire quantity, inversion, saving and percentage of annual income that represent of investment, by municipality in MM CLP[8]

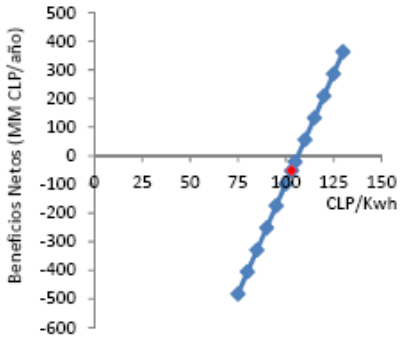
	Comuna	Luminarias	Inversión	Ahorro Anual	Inversión/ Ingresos (1)
Antofagasta	Calama	10,000	1,263	131	2.24%
	Antofagasta	17,595	2,282	295	1.47%
	Tocopilla	1,745	228	30	2.49%
	Mejillones	823	107	14	0.77%
	San Pedro de Atacama	780	99	0	0.88%
	Taltal	1,100	146	24	0.84%
	Ollagüe	67	9	1	0.27%
	Sierra Gorda	3,300	437	66	2.48%
	Maria Elena	100	13	1	0.18%
Atacama	Copiapó	17,500	2,180	218	3.53%
	Freirina	1,200	150	13	3.04%
	Caldera	2,276	284	26	2.42%
	Chañaral	2,703	336	29	3.53%
	Alto del Carmen	1,055	129	10	1.56%
	Vallenar	6,585	821	77	4.09%
	Tierra Amarilla	1,934	240	23	1.55%
	Diego de Almagro	1,422	180	34	1.29%
	Huasco	1,369	170	19	2.32%
Coquimbo	Coquimbo	18,000	2,266	222	2.64%
	La Serena	19,584	2,449	238	2.50%
	Ovalle	7,639	952	87	3.04%
	Monte Patria	3,679	456	32	4.37%
	Los Vilos	2,439	303	26	2.69%
	Vicuña	3,615	443	26	4.38%
	Andacollo	1,435	180	14	3.16%
	Illapel	2,024	250	17	1.73%
	Salamanca	2,500	308	22	1.92%
	Río Hurtado	674	83	5	1.87%
	Combarbalá	1,500	184	11	2.80%
	La Higuera	900	110	6	1.91%
	Punitagui	1,111	137	9	3.02%
	Canela	953	116	6	2.14%
	Paiguano	425	52	3	1.07%

The following Figure shows a sensitivity analysis of the net annual evaluation against different values of energy prices, energy savings from bi-level ballast, the lamp life and luminous efficiency (lumens / watt) SAP technology considered in the replacement of public lighting fixtures. The red dot shows the basis of the evaluation stage, associated with an annual net profit of -52 MM CLP for the three regions analyzed.

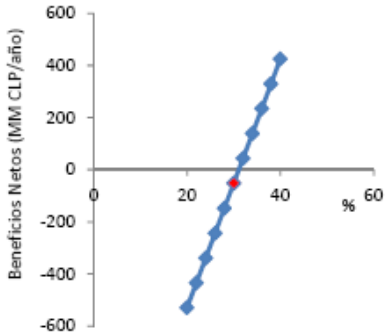
[8] The income of the Municipalities is information for the year 2011, downloaded from the official website the National Municipal Information System (SINIM), considering all available accounts in the Budget Classifier. Consulted on 27-09-2012.

Figure 5. Sensitivity analysis for the evaluation parameters

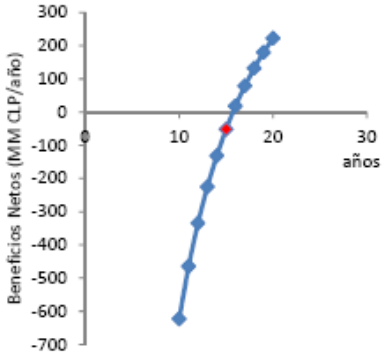
a) Energy prices



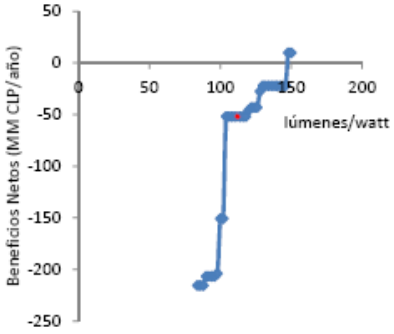
b) Saving of the ballast



c) Useful life of the Luminaire



d) Lumens7watt SAP Technology



E. Choosing the best regulatory alternative

The valuation performed corresponds to the replacement of public lighting, which is the main source of light pollution in the regions covered. The results of the study conclude that the replacement of luminaires involves a significant initial investment for the regions in question, totaling $ 36 million, which was offset by savings from lower operating costs and maintenance of the new lights, which amounted to $ 3.6 million per year. In sum, we find that the replacement project involves a total cost in present value of $ 1 million for the three regions involved. Note that these are costs to be assumed by the public sector, while the benefits accrue mainly to private.

Although the replacement of public lighting costs represent for the regions analyzed, a possible extension of national legislation can lead economic benefits from energy savings, depending on the base composition of the park, which due to the lack of regulation in the rest the country should have a lower efficiency than in the regions analyzed. Finally, from the public consultation of the draft revision of the standard, with additional background information of this work raised and modifications were made to the draft standard, mainly on spectral radiances regulated sources.

F. Final remarks

Importantly energy savings involves other indirect benefits such as reduced GHG, aligning well with the National Energy Strategy. I noted above suggests benefits of extending this policy to the entire national territory.

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H. Problems the regulator faced when evaluating the regulatory impact.

There is need for inventories of public lightning, luminous signs and luminaries from big enclosures (e.g. stadiums). This need required a search throughout a State purchase portal and information about supervision to generate relevant information regarding necessary inventories for estimations both of impacts and costs.

Matter of regulation	**Vehicle Licensing Reform: Warrant of Fitness (WoF)**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method (**X**) VSL (**X**) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	( ) Sensitivity analysis ( ) Immediate Rate of Return (**X**) Other, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal Rate of Return

Case 5. Vehicle Licensing Reform: Warrant of Fitness (WoF)

A. Introduction

The Vehicle Licensing Reform (VLR) project is a joint project undertaken by the Ministry of Transport and the NZ Transport Agency. It looks at the Annual Vehicle Licensing (AVL), Warrant of Fitness and Certificate of Fitness (WOF and COF) and Transport Services Licensing (TSL) regimes. The primary purpose of the review is to reduce compliance and administrative costs, while achieving similar or improved safety and environmental outcomes.

New Zealand government documents the national cost benefit analysis (CBA) used to inform the development of policy options for changing the frequency of WOF. The report covers most of the core components of the regulatory impact assessment required by the Treasury. The CBA model is also being used, with some modifications, to evaluate proposed changes to the COF regime for light and heavy commercial vehicles.

B. Identification of the problem

With around 4.2 million vehicles on the road in New Zealand, **meeting inspection requirements adds up to a considerable time and cost burden for households and businesses**. Vehicle inspections are intended to reduce road crashes that may result from vehicle defects, and reduce consequential social costs of deaths or injuries. Nearly all light vehicles are inspected for roadworthiness and issued a WOF. There are around 5.6 million WOF inspections annually (excluding rechecks).

The policy problem is whether the costs of the frequency and scope of the current WOF inspection requirements are equal to, or exceed, the benefits obtained from avoiding the social cost of crashes. There are several reasons to believe the current policy setting might not be optimal. These include the fact that **New Zealand has the most stringent inspection within the OECD countries**, and that several states in Australia only require inspections at vehicle sale and do not appear to record higher crash rates attributed to vehicle factors than New Zealand.

The policy and economic argument for mandatory vehicle inspections relies on the idea that vehicle maintenance (of safety features) reduces accident rates and hence lowers the social cost of road crashes. The proposition is that vehicle owners do not capture the full benefits of safety servicing and have sufficient incentive to take account of the crash risk they impose on others from insufficient maintenance. In this sense, the **Ministry of Transport have record of a significant percentage of vehicles in roads no meeting roadworthiness standards to reduce the incidence and severity of crashes caused by defects.**

Also, the stringency of the regime and the substantial improvements in vehicle technology and durability raise questions as to whether the regime could be better targeted to risk, and the likely costs and benefits of doing so.

According to the above, we can state that government intervention is necessary in order to overcome two main problems: the **market failure** that arises from the negative externality in safety caused by the lack of incentives to maintain vehicles in the optimum; and the **government failure** that arises due to a discrepancies in the stringency of current regulation and the present conditions and practices in vehicular maintenance and safety

C. Objectives of the intervention

The overall objective of the regulatory proposal is to **reduce regulatory burdens caused by the stringency of vehicular inspections while achieving similar or improved safety outcomes.** Other objectives of the intervention are the following:

- Support the government's economic growth and regulatory reform agendas by reducing regulatory burdens while achieving similar or improved safety and environmental outcomes
- Align the costs of regulatory intervention for operator and vehicle inspection requirements to safety risks and benefits
- Reduce associated compliance and administrative costs
- Achieve net benefits from any change and avoid unintended consequences.

D. Regulatory alternatives

At present, light vehicles are required to have annual inspections until 6 years of age and 6-monthly inspections thereafter. New Zealand government through Treasury and the Ministry of Transport, proposed a Vehicle Licensing Reform. A discussion document was released on 19 September 2012 to consult the public on five less frequent and less stringent WoF inspection regimes:

- ***Option 1****: Annual inspections to vehicles under the age of 12 years, with six-monthly inspections thereafter*. This option includes:
  - Information and advice programme
  - Changes to how vehicle infringements are dealt with
  - Introduction of demerit points for operating an unsafe vehicle

- ***Option 2****: No inspection for first three years of vehicle age, and then once a year thereafter.* This option includes:
  - Improved test for all vehicles
  - First inspection at three years of age, with annual inspections thereafter
  - Information and advice programme
  - Greater use of compliance technology
  - Better targeted compliance and enforcement activities
  - Changes to how vehicle infringements are dealt with
  - Introduction of demerit points for operating an unsafe vehicle

- ***Option 2A****: Same as Option 2 but 6-monthly inspections for vehicles manufactured before 1 January 2000.* This option implies:
  - Improved test for all vehicles

- First inspection at three years of age, annual inspections for vehicles manufactured after 1st January 2000 and six-monthly inspection for vehicles manufactured before 1st January 2000.
- Information and advice programme
- Greater use of compliance technology
- Better targeted compliance and enforcement activities
- Changes to how vehicle infringements are dealt with
- Introduction of demerit points for operating an unsafe vehicle

- ***Option 3****: Inspection frequency based on vehicles kilometers travelled (first inspection at 50,000 km and then once every 12,000 km) or every three years (whichever comes first)*. This option implies:
  - Improved test for all vehicles
  - First inspection at 50,000 km, then every 12,000 km thereafter
  - A default inspection for vehicles that have not had an inspection within three years
  - Information and advice programme
  - Increased and better targeted compliance and enforcement activities
  - Changes to how vehicle infringements are dealt with
  - Introduction of demerit points for operating an unsafe vehicle

- ***Option 4****: Inspection only on change of ownership (similar to some Australian States).* This implies an inspection frequency of two years on average for vehicles up to six years of age, and every three years for older vehicles. This option implies:
  - Improved test for all vehicles
  - No periodic inspection
  - Inspection at change of ownership or if required following an inspection order
  - More comprehensive information and advice programme
  - Increased and better targeted compliance and enforcement activities
  - Improvements to how we deal with vehicle infringements
  - Introduction of demerit points for operating an unsafe vehicle

E. Impact evaluation

The regulator applies a Cost-Benefit analysis to assess the impact of the potential solutions to the identified problem.

Assumptions of the CBA approach

- Discount rate: 8%
- Time horizon: 30-years
- Applies the Ministry of Transport‘s fleet growth projection forecasts to calibrate future benefits
- Annual safety costs are extrapolated into the future using forecasts of the road toll (fatal and injury crashes) continuing to decline and flatten out.

The CBA approach considers the following costs and benefits of vehicle inspection:

Cost / Benefits	Description and assessment
Consumer charges, compliance costs and avoidable repair costs	Willingness to pay of consumers for safety inspections of vehicles, the consumer demand and the regulatory burden (mainly inspection costs)
Safety and the associated traffic delay impacts from road crashes	First, the risk line was estimated using empirical data, second the impact of incremental cost attributed to road crashes was estimated and, then disaggregate the estimated number of injury crashes by crash severity, finally the social cost of road crashes including allowance for non-injury crashes was obtained. In general, road crashes have financial and economic impacts through factors like direct medical costs, loss of output and reduced quality of life, vehicle damage, justice and crash investigation.
Environmental and fuel saving benefits from emission reduction policies	Social cost of anthropogenic (man-made) sources of air pollution.
Justice and enforcement costs	Here, the regulator considers that infringements have significant flow-on costs for the justice system. With alternative inspection frequencies, this cost may reduce. Analysis takes into account the national resources costs of supporting the WOF regulatory regime; including: • Enforcement and collection resources for TLAs and police • Costs to the Justice system (Courts and Corrections) • Costs to offenders.

a. Consumer charges, compliance costs and avoidable repair costs

Table 1 below summarizes the net effect on consumer costs and charges of the four options analyzed. Reducing the frequency of inspections initially saves between $35 million and $172 million on “charges”, which measure the economic resources saved. There are also estimated to be between $15 million to $68 million in annual savings in inconvenience and compliance costs. This represents the **value of time saved by vehicle owners**, which could be used for productive use (i.e. at work), or could be used for leisure (from which people benefit).

Table 2: Consumer charges, compliance costs and avoidable repair cost

Annual savings	Option 1	Option 2	Option 2A	Option 3	Option 4
Savings in charges	$35m	$117m	$107m	$116m	$172m
Savings in compliance costs	$15m	$48m	$45m	$48m	$68m
Savings in avoidable repair costs	$6m	$19m	$18m	$18m	$31m
Total consumer savings	*$55m*	*$183m*	*$169m*	*$182m*	*$207m*

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

b. Safety and environmental effects

In New Zealand, vehicle factors (WOF and non-WOF related) contributed to (but did not necessarily cause) about 6% of fatal crashes and 3.5% of all fatal and injury crashes for the three years previous to 2011. WOF-related defects contributed to 2.5% of fatal and injury crashes over this period. Approximately 0.4% of all injury crashes were those with such defects cited as the “sole” cause of the crash.

At this point it is important to mention that the methodologies used to monetize the safety and the environmental effects were both the Value of Statistical Life (VSL) and the Disability Adjusted Life Years (DALY). The last, because regulator's input data are statistics about life losses and people injured due to crashes related to vehicle deficiencies.

The CBA provides the risk of an increase in crash rates, and associated social costs, from reduce inspection frequencies. Table 2 summarizes the estimated annual social costs, for each regulatory option, of road crashes. These range from $5 million to $63 million for the options analyzed. These estimates include the likely benefits from voluntary uptake of safety checks under the policy options. The estimated increase in annual total social cost of road crashes for option 4 is the highest. This is because under this option the entire WOF vehicle fleet would be affected, and because the average inspection frequency for vehicles over six years of age would be three years — one sixth of the current six-monthly frequency.

Table 3: Estimated safety impacts (with no added safety mitigation)

Annual costs	Option 1	Option 2	Option 2A	Option 3	Option 4
Estimated increase in annual total social cost of road crashes	$5m	$17m	$13m	$21m	$63m
Percentage increase in annual total social cost of road crashes	0.1%	0.4%	0.3%	0.5%	1.6%

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

There are two caveats with the results:

- The estimates do not include the effects from mitigation measures that are being developed for implementing the options
- No assumption has been made to allow for any changes in vehicle maintenance behaviors over and above those considered under the voluntary safety check assumptions.

c. Justice and enforcement costs

Many vehicle owners do not comply with the inspection requirement by the WOF due date – in fact 25% of people have still not complied by one month after the dateline. Some of the unwarranted vehicles may be taken out of the fleet temporarily due to repairs. However, survey evidence and crash reports suggest that many of the unwarranted vehicles may still be in use, at least for a short period of time. When detected, infringement notices are issued by NZ Police and territorial local authorities.

Infringements have significant flow-on costs for the justice system. Our analysis takes into account the private and public resource costs (excluding fine revenues as these are transfer payments) associated with offence detection, infringement processing, collection and enforcement. It is expected that a change in the inspection frequency will reduce the burden to vehicle owners and therefore reduce the risk of non-compliance and related infringements. Estimates of likely savings assume the volume of infringements is proportionate to the inspection frequency and vehicle defect infringements will increase with a reduction in inspection frequency.

Table 4: Estimated net reduction in social cost of WOF and vehicle defects-related infringements Annual savings

Period	Option 1	Option 2	Option 2A	Option 3	Option 4
In year 1	$1.0m	$3.4m	$1.7m	$3.3m	$4.8m
From year 7	$1.6m	$5.3m	$3.4m	$5.1m	$7.8m

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

F. Choosing the best regulatory alternative.

Overall Results

In the tables below we can see a summary of the described benefits and costs of the regulations, as well as it present value in a time horizon of 30 years at an 8% discount rate. Also, as a part of the assessment process we report the Benefits-Cost Ratios.

Table 5: Summary of present value costs and benefits

Costs and benefits	Option 1	Option 2	Option 2A	Option 3	Option 4
Reduction in avoidable repair costs	$68m	$231m	$200m	$225m	$376m
Reduction in WOF charges	$430m	$1436m	$1201m	$1430m	$2121m
Reduction in WOF compliance costs	$179m	$588m	$500m	$592m	$833m
Reduction in infringement enforcement costs	$16m	$55m	$36m	$53m	$80m
Sub-total of benefits (i.e. excluding crashes)	$.69b	$2.31b	$1.9b	$2.30b	$3.41b
Increase in social cost of road crashes	-$54m	-$174m	-$151m	-$212m	-$630m
Net present value (NPV)	*$0.6b*	*$2.1b*	*$1.8b*	*$2.1b*	*$2.8b*
Benefit cost ratio (BCR)	*13*	*13*	*13*	*11*	*5*

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

Table 6: Summary of net present values and benefit-cost ratios

	Option 1	Option 2	Option 2A	Option 3	Option 4
Present value of benefits	$0.69b	$2.31b	$1.94b	$2.30b	$3.41b
Present value of costs	$54m	$174m	$151m	$212m	$630m
Net present value (NPV)	*$.64b*	*$2.14b*	*$1.79b*	*$2.09b*	*$2.78b*
Benefit cost ratio (BCR)	*12.9*	*13.3*	*12.8*	*10.8*	*5.4*

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

While the high benefit-cost ratios (BCRs) may appear surprising, they are not inconsistent with international studies that do and do not support periodic inspection. For instance the 1999 Australian Federal Office of Road Safety Study estimated a BCR of 0.35 for introducing annual inspections. A comparable estimate here is to move from Option 4 to Option 2, which results in a smaller incremental BCR.

In particular, studies that support more frequent inspections have often not considered issues such as enforcement costs, inconvenience costs and avoidable repair costs. There are also significantly lower charges for inspection in most of these studies, which may reflect a more limited scope of safety inspections than the WOF regime or more competitive vehicle servicing markets.

NPVs are the preferred report measure and are recommended in the Treasury's Regulatory Impact Analysis handbook, that is why in this case, NPV is the main criteria to choose the best regulatory alternative. Nevertheless, BCRs are helpful to convey "bang for buck", a higher BCR of one option over another does not necessarily mean it is better, because BCRs fail to convey the absolute size of benefits and costs.

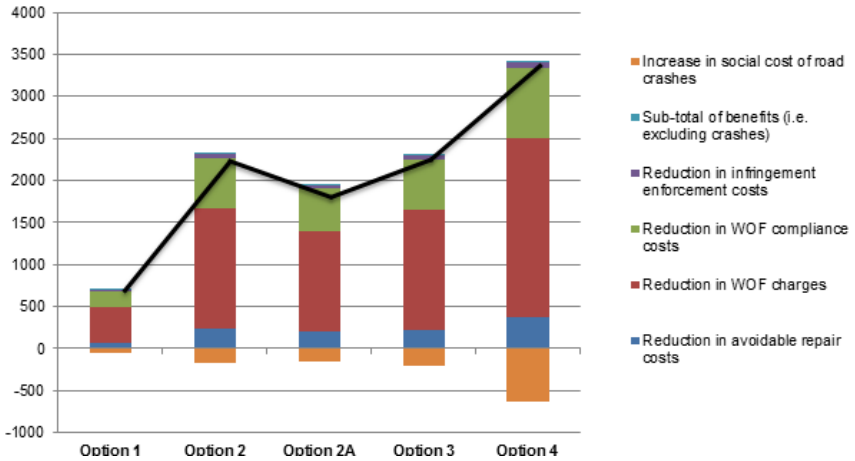
Table 6 provides the contribution of each category of benefits and costs to the NPV for each option.

Table 7: Contributions of impact areas to option NPVs

Impact area	Option 1	Option 2	Option 2A	Option 3	Option 4
Reduction in WOF charges3	67%	67%	67%	68%	76%
Reduction in WOF compliance costs	28%	28%	28%	28%	30%
Increase in social cost of road crashes	-8%	-8%	-8%	-10%	-23%
Reduction in avoidable repair costs	11%	11%	11%	11%	14%
Reduction in infringement enforcement costs	3%	3%	2%	3%	3%
Total	*100%*	*100%*	*100%*	*100%*	*100%*

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

Figure 1: Net present values for WOF options (2013 to 2042)



Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

Regulatory **options 1 to 4 reports NPV > 0** which means that its implementation increase social welfare because **benefits of issuing this proposals overweight its costs**. Nevertheless, BCRs shows that even while option 4 has largest national benefit, it is also the most costly and the less effective in meeting reform policy objectives of achieving similar or improved safety outcome. In this sense, the regulator decided to applied a "least regret" approach that favors either Options 1 (annual inspections up till age 12 then 6 monthly) or 2 (first inspection at 3 years and then annual inspection) or 2A (same as Option 2 but 6-monthly inspection for vehicles manufactured before 1 January 2000

Sensitivity analysis

In order to prove the robustness of the results obtained in the impact evaluation, we proceed to elaborate a **sensitivity analysis**. The most important parameter in terms of benefits is the *savings from reductions in WOF charges* that account for between 67% and 76% of the NPVs as presented in Table 6 above. Sensitivity to changes in these charges is not reported because they are based on regular industry surveys and there is very little uncertainty concerning their estimation.

Sensitivity assessments for some of the other key assumptions are listed in Table 7 below. Although some assumptions appear to be important in absolute terms, many are unimportant over the range tested relative to the total NPVs estimated. These include:

- Servicing frequency assumptions
- Value of time used for obtaining a WOF adjusted for work-leisure split assumptions
- Savings from avoided maintenance costs associated with over-serving.

Table 8: Confidence intervals of NPVs

	Option 1	Option 2	Option 2A	Option 3	Option 4
Minimum	$0.4b	$1.3b	$1.1b	$1.3b	$1.5b
5th percentile	$0.5b	$1.6b	$1.4b	$1.6b	$2.0b
Mean	*$0.6b*	*$2.1b*	*$1.8b*	*$2.1b*	*$2.8b*
95th percentile	$0.7b	$2.4b	$2.1b	$2.4b	$3.3b
Maximum	$0.8b	$2.8b	$2.4b	$2.8b	$3.9b

Source: (Cost Benefit Analysis Report: warrant of fitness reform options, 2012)

Monte Carlo simulation was used to estimate the range of the NPV results. The broad orders of magnitude of net-benefits for each option are relatively stable. With 90% confidence, the range of NPVs for options 1 to 4 respectively are $0.5–$0.7 billion, $1.6–$2.4 billion, $1.4-$2.1 billion, $1.6–$2.4 billion and $2.0–$3.3 billion respectively.

According to the last, we can state that the analysis is very sensitive to applying a discount rate that is higher or lower than the Treasury default rate of 8%, nevertheless, all the alternatives keep having a **NPV > 0**, which supports the robustness of the regulatory proposal.

G. Final remarks

The key findings of the analysis include:

- There are significant consumer savings from reduced WOF charges, compliance cost and avoidable repair costs. In total, these savings are estimated at between $54 million per year for option 1 and $266 million per year for option 4.
- While reducing the inspection frequency risks an increase in road crashes, the effects are relatively small. The estimated increase in the total social cost of crashes of the options ranges from $5 million for option 1 to $63 million for option 4 per year. This represents 0.1% to 1.6% of the current annual total social cost of road crashes.
- The annual savings associated with enforcing and managing WOF-related infringements is estimated at between $1.6 million for option 1 and $7.8 million for option 4 from year 7.
- The NPVs of the options range between $0.6 billion for option 1 and $2.8 billion for option 4, discounted at 8 percent.
- Sensitivity analysis found that:

    - The NPVs are most sensitive to the discount rate used; but even under the highest discount rate the NPVs continue to be significantly greater than zero.
    - The NPVs are also sensitive to the inconvenience time taken to obtain a WOF but the NPVs continue to be high under all scenarios.
    - Allowing for under-recording of WOF-defects in crash reports does not materially impact on the overall NPVs.

The results of the cost-benefit analysis unambiguously support reducing the current frequency requirement of WOF inspections for light vehicles. The results are robust, with the most substantial benefits flowing from firm estimates of savings in charges, adjusted to reflect the expenditure on safety checks that likely would occur anyway. On the risk side of the ledger, we have adjusted for potential under-recording of safety related vehicle defects in crash reports and this has had an insignificant impact on the results.

H. References

Ministry of Transport. *Cost Benefit Analysis Report: warrant of fitness reform options*. (December 2012). NZ Government. Can be found at the following links:

http://www.treasury.govt.nz/publications/informationreleases/ris/pdfs/ris-transport-vlr-jan13.pdf

http://www.transport.govt.nz/ourwork/Land/Documents/Cost-Benefit-Analysis-WoF.pdf

Matter of regulation	***Unified Enterprise Law and Common Investment Law: focus on the replacement of the existing licensing mechanism with a registration system applicable to foreign investors***

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	( ) Social regulation (**X**) All indistinctly

Implemented method (s) *(You can choose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can choose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method ( )VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( )Method of human capital ( )Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	( )Sensitivity analysis ( ) Immediate Rate of Return (**X**) Other, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal Rate of Return

Case 6. Unified Enterprise Law and Common Investment Law: focus on the replacement of the existing licensing mechanism with a registration system applicable to foreign investors

A. Introduction

On July 2005, Vietnam finished the 9th round of negotiations to accede the World Trade Organization (WTO), and began stepping up its efforts to become a WTO member by the end of the year. In preparation for accession, the Government committed itself to revising or issuing 22 laws and subordinate laws in order to comply with WTO requirements and commitments and with other bilateral trade agreements, particularly with the agreed principles related to national treatment (NT) and most-favored nation (MFN), businesses, taxes, customs and intellectual property.

In this context, the need for reforms and improvement of the legal framework and policies, particularly of those related to businesses and business environment became more imperative than ever. Its improvement is key to enhancing the quality, efficiency and competitiveness of the national economy, especially when Vietnam integrates itself fully into the world economy.

This study case presents the impact evaluation of a regulatory proposal about the conditions of investment climate in Vietnam. To do this, as first step, we introduce and describe the problem identified as well as the failures that it causes in economy and society; then we identify the objectives of the government intervention and the regulatory alternatives that could help to overcome the problem; then we present an assessment of each of the alternatives that includes identification and description of its costs and benefits; finally we obtain the net benefit in order to choose the best regulatory proposal.

B. Definition of the problem

In 2005, Vietnam had different laws to regulate different types of enterprises (classified by economic sectors, ownership structure or nationality). State-owned enterprises were subject to the State-owned Enterprise Law, and the Enterprise Law regulates domestic enterprises registered in the form of sole proprietorship, liability limited company, partnership or joint-stock company. Cooperative Law governs cooperatives. Foreign Direct Investment Law provides a legal framework for licensing, incorporation, operational scope, and investment incentives applicable to foreign invested enterprises (FIEs) while Domestic Investment Encouragement Law provides a legal framework and incentives for domestic investments. In addition, enterprises operating in a certain sector and industry were also regulated by sector laws or subordinate laws on the sector.

The last means that enterprises of different ownership and/or nature were treated differently in terms of access to land, credit, trading rights, construction, among others. As a result, **the business environment in Vietnam used to be perceived as inconsistent, unfair, unpredictable, unstable and inconsistent with WTO requirements**. Such legal constraints were hampering the development of enterprises and jeopardizing the government's management. Also, in order to keep its membership to the WTO, Vietnam must guarantee that all business –regardless of their ownership and nationality– are treated equally and fairly.

According to the Foreign Investment Law, FIEs must complete a **complicated and costly licensing process** in order to be established and start operations. To get an investment

license, FIEs must complete several procedures and succeed in obtaining various written approvals from many sectoral government bodies. This implies a **major constraint to FIE market entry**, which adversely affects the competitiveness of the investment climate in Vietnam

The problem described above show the need for government intervention in order to overcome the **market failure** that arises from the complexity that involves entry to FIE market (entry barriers), and the **government failure** that results from the heterogeneity in regulating enterprises according to its ownership and/or nature.

C. Objectives of the intervention

The main objectives of the government intervention are the following:

- Guarantee that all businesses and investors are treated equally and fairly in a transparent, stable and predictable legal environment;
- Ensure competitiveness within the investment climate;
- Encourage the development of enterprises;
- Provide a public management tool for the citizens and foreigners to exercise their rights and freedom to do business under the best conditions, and
- Improve the effectiveness and efficiency of government's management.

D. Regulatory alternatives

- ***Baseline scenario (not issuing regulation).***

This option implies the no government intervention in the investment market, which means that the identified problems will continue happening. Under this scheme it is expected to:

- Regulate enterprises differently, according to the sector they belong and its nationality.
- Keep entry barriers to new businesses and investors.
- Disrespect WTO principles and requirements.
- Delay the entry of Vietnam to global trade.
- Decrease of foreign and national investment due to uncertainty in the business climate.

- ***Emission of Unified Enterprise Law (UEL) and Common Investment Law (CIL).***

Vietnam's Government proposed the issuance of two primary laws in order to improve the investment climate and to fully respect bilateral, regional and multi-lateral agreements. These laws are the UEL and CIL which will be applicable to all types of enterprises operating in Vietnam, regardless of their ownership and nationality. In July 2004, the Prime Minister issued the *Guiding Principles of the UEL and CIL* as the basis for the drafting of the laws in order to simplify its assessment.

These Guiding Principles specify the key principles of the two laws and require the improvements in the way and methods under which the laws were prepared. Also, it

strongly emphasized on the consultation with the business community and different interest groups to ensure the high quality of the laws.

The key principles established in these two laws are:

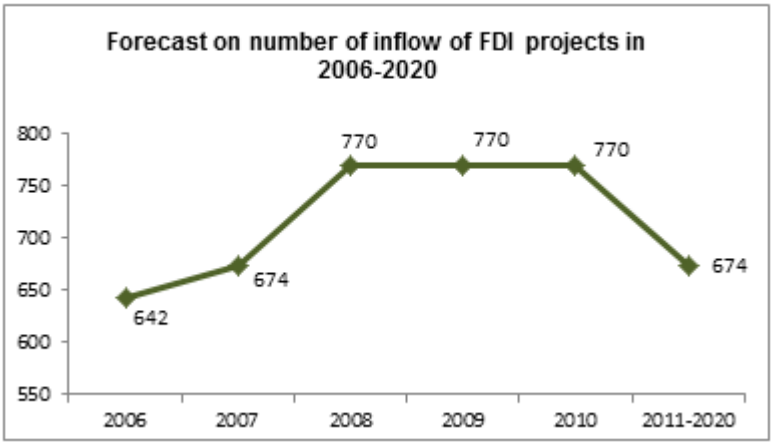
1. Both laws are applicable to the four main types of enterprises including liability limited company, Shareholding Company, partnership and sole proprietorship.
2. Establishment of a new, more effective and nation-wide online business registration system that have to be applied consistently, in a unified manner to all types of enterprises.
3. The reserved list or negative list of sectors in which business are prohibited from or allowed only under certain conditions will be announced in a transparent manner.
4. All type of investment plans have to be made in a public and transparent manner, and regularly updated.
5. Enterprises have to operate under the following forms: liability limited company, Shareholding Company, partnership or sole proprietorship. Foreign investors are no longer restricted to the form of a liability limited company; they are free to choose among the four possible legal forms.
6. The removal of the requirement related to the consensus in decision making by the Board of Directors.
7. Limits on the number of foreign workers in a company will be abolished.
8. Limits on foreign ownership in domestic enterprises will be abolished.
9. Post-registration inspection in mandatory for all enterprises.

E. Impact evaluation

The regulatory impact evaluation of the Guideline Principles, with focus on the replacement of the existing licensing mechanism with a registration system applicable to foreign investors, was made through a Cost-Benefit Analysis.

Cost-Benefit Analysis assumptions

- The analysis is focus on assess whether the major proposed reforms introduced through the UEL and CIL are in the national interest.
- **Qualitative costs and benefits** are mentioned to take them into account; nevertheless, the major calculation is made on obtaining the net economic impact of the replacement of the existing investment licensing mechanism with an investment registration system applicable on national and foreign investors.
- **Time horizon:** from 2006 to 2020
- **Evaluated scenario:** After the promulgation of the UEL and CIL, the number of inflow FDI projects will increase substantially as a result of the improvement in the legal framework and stable economic growth. The number of inflow of FDI will supposed to increase steadily from 2006 onwards, reaching 750-800 projects/ year in 2007-2010, and then staying at a stable level of 650-700 projects/year from 2011-2020.



- **Data:** The methods used to obtain the necessary data for the analysis were desk research, expert consultation, business impact test panels, business poll, and in-depth interviews with enterprises.
- **Composition of FDI projects by categories:** According to the poll, FDI projects were classified into three categories and each has different structures of costs spent on obtaining and investment license. The three categories are:
  - Category 1: Includes large scale projects with investment in sensitive sectors and requires appraisal and approval by MPI or agreement from the prime Minister. Account 7% of total.
  - Category 2: Includes investment projects in normal manufacturing and service sector which under the licensing authority of the Provincial People's Committee. Account 57% of total.
  - Category 3: Includes projects with investment into the Industrial Zone (IZ), the Export Processing Zone (EPZ). Account 34% of total.

- ***Baseline scenario (not issuing regulation).***

This scheme implies that all the investors interested in obtaining an investment license should follow one of the following processes: (i) appraisal for issuance; and (ii) registration for issuance. Both cases imply the compliance of several requirements that generate an administrative burden and large opportunity cost to individuals.

1. Qualitative costs of no issuing regulation

a. Registration for Issuance of Investment License.

To be eligible to the registration, a prospective investment project should meet the below conditions:

- Not being listed as a Group A project[9];

[9]The appraisal of Group A Investment Project requires the involvement of 8-10 ministries which each contributes 7 experts in providing comments and judgments. In total, around 50-70 person are involved in appraising the project. If the experts and senior managers, leaders from the Ministry of Planning and Investment (MPI) and the Government office are included, the appraisal figure will well reach 100 valuators.
In the case of Group B Investment project, its appraisal is less complicated but still requires approximately 60 experts from MPI and other ministries and agencies to be involved. Among them it is estimated that 10 are from the Foreign Investment

- Being relevant to an approved product development or sectoral development plan;
- Not being listed in the list of Project Requiring Environment Impact Assessment;
- Exporting more than 80% of its product, or
- Being located in an industrial zone; not being included in Group A Project List, but in Especially Encouraged Investment Project List or Encouraged Investment Project List, or
- Being in the manufacturing sector with investment capital of up to 5 million USD.

Also, projects which only need to be registered for issuance of investment license should prepare 5 sets of application documents, original and 5 copies. Each set of documents should include:

- Application for investment license
- Joint venture contract and charter of the prospect joint venture enterprise, or charter of the prospect 100% FIE or of the business cooperation contract; and
- Documents certifying the legal status and financial health of the related parties.

In case of foreign investors is also necessary to submit the following:

- Legal documents testifying the establishment of their enterprise
- Evidence on the financial support by the holding company

All projects which fail to meet the conditions applicable for the registration for issuance of investment license should be appraised to obtain an investment license.

b. Investment License Application Document.

Investors should prepare 12 copies of application documents in the case of Group A Project, and 8 copies for projects of other categories (one of these is the original). Each of the copies should include papers as required in the document to register the issuance of investment license. Additionally, the investor must submit:

- A feasibility study
- If applicable, other documents related to technology transfer

Investors are required to provide additional documents depending on different cases:

- Environment impact assessment
- Documents related to the land use
- Agreements and/or contracts related to the investment project
- Preliminary architecture design of the construction works as part of the feasibility study

The described licensing process, either registration or issuance, reveals several constraints to investors that will continue to happen under the scheme of “no issuance of regulation”:

Agency (under MPI), 5 from provincial People’s Committees, and the rest from other relevant ministries and agencies with each contributing 7 experts.

- Many requirements are seen to be far from international best practices, for example, the required document certifying the financial status.
- Feasibility studies are most of the time an inefficient formality, since investors often hide their real calculations related to market, technology, and project management.
- Due to a lack of concrete stipulations on the feasibility study, most investors are subject to the discretion of the appraisal bodies.
- Investors have to meet at least 11 different institutions to present or to justify a project.
- Besides documents and documents required, prospective investors are often asked to provide additional documentation to justify the decisions of relevant agencies.
- The perceived level of complexity to obtain relevant written approvals in applying for investment license is too high.
- According to the business survey, on average, it takes investors 60 days from the moment the moment the investment license application document is submitted until the investors are granted with an investment license.
- Investors report to spend about 80 days on paper works in the process to obtain a license.

2. Costs that foreign investors have to pay under the no regulation scheme (described licensing mechanism)

The methodology used to quantify the costs that foreign investors have to pay under the no regulation scheme, was the Standard Cost Model, which implies: 1) the identification of the requirements generated for complying with the formalities in the described scheme; 2) the identification of the activities to be carried out in order to fulfill each of the requirements; 3) Quantification in monetary terms of each of the requirements 4) Identification of the individuals that will have to comply with the obligation.

Cost item	Category 1	Category 2	Category 3
Legal consultancy	6,000	3,000	2,000
Development of feasibility study and application document	10,000	5,000	4,000
Cost related to travelling, accommodation for staff working on the project	40,000	20,000	15,000
Paperwork, preparation of papers certifying legal and financial status	500	500	500
Informal expenses (reception, presentation, etc.)	10,000	5,000	5,000
Total	*66,500*	*33,500*	*26,500*

- ***Emission of Unified Enterprise Law (UEL) and Common Investment Law (CIL).***

This alternative involves the emission of two primary laws to regulate equally and fairly all enterprises and investors either nationals or foreign. With the regulatory proposal, Vietnam's Government looks to comply with the following objectives:

- Development of a more competitive economy and a more equitable society

- Regulation without any discrimination in terms of ownership and in terms of economic sectors
- Market entry will be lowered
- Encourage the foreign investment
- Reduction of the costs related to licensing investing projects

a. Qualitative benefits of the regulation

- The business freedom is strengthened; it will provide autonomous and free market entry to investors.
- Clear stipulations on the prohibited or restricted business sector will help to promote investment and create employment in other sectors.
- Transparency in the list of restricted sector to inversion will encourage enterprises to be better prepared in order to be eligible to operate in the restricted business sectors.
- Fairer accessibility of investors to all type of planning information will result in overcoming information asymmetry and inequities between different investors.
- Framework conditions on corporate governance will be better defined and consistently applied to all type of enterprises.
- Excessive interventions into the operation and business of foreign invested enterprises will be reduced, allowing FIE's to respond more effectively and promptly to changes in the market and in the business environment.
- The principle of "non-discriminatory treatment towards investment" will allow domestic enterprises to gain an easier access to foreign capital and technology.
- The replacement of the existing investment licensing mechanism will reduce administrative and implementation costs, lower risks, improve the service of public agencies and improve the image of a business friendly government.

b. Costs of implementing the regulatory proposal

Operationalizing a business registration system that can be consistently applied to all types of enterprises will require some additional costs, particularly to establish new procedures and to improve the national business registration system. Such costs include:

- Training operational staff in relevant fields and on how to implement the new system;
- Expenses related to the adjustment of related strategies and to the revision of sectoral strategies;
- Public investment to monitor implementation and enforcement of the new system, and
- Expenses to build the capacity needed to implement the new laws.

c. Costs that foreign investors have to pay under the new investment registration system

Cost item	Category 1	Category 2	Category 3
Legal consultancy	5,000	2,000	2,000
Development of feasibility study and application document	10,000	10,000	10,000
Cost related to travelling, accommodation for staff working on the project	500	500	500
Paperwork, preparation of papers certifying legal and financial status	2,000	2,000	2,000
Total	*17,500*	*14,500*	*14,500*

F. Choosing the best regulatory alternative

According to the above calculations, it is possible to obtain the total reduction in costs by foreign investors for each typical project in the scenario that the investment registration is applied, this is, the net benefits of the regulatory proposal. The net benefit is obtained through the difference between the costs that foreign investors have to pay under a scheme of no regulation and the costs that foreign investors have to pay under the regulatory proposal.

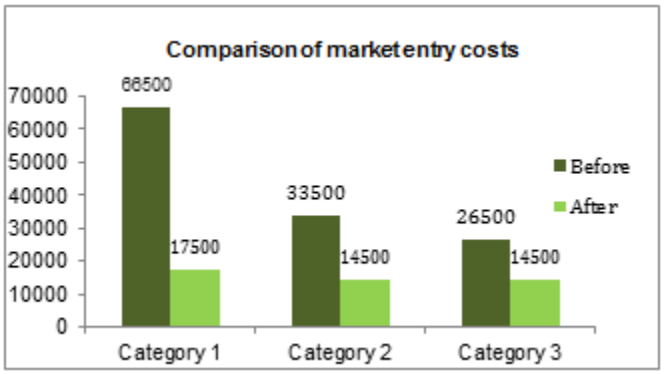
Benefit (reduction of costs) **=** **Costs that have to be paid under scheme of no regulation – Costs that have to be paid under the regulatory proposal**

Cost item	Category 1	Category 2	Category 3
Benefit (Reduction of costs per year)	*49,000*	*19,000*	*12,000*

On the basis of the assumptions mentioned, the total reduction in entry costs for foreign investors as a result of the replacement of the licensing mechanism with a registration system is estimated at 12 million to 14 million USD. This is the result of:

NET BENEFIT = Reduction of costs per year x No. investment projects

Project categories	Annual reduction in entry costs		
	2006	2010	2011-2020
Large-scale projects which should have been under the licensing authority of MPI	2,312,163	2,642,472	2,312,163
Projects which should have been under the licensing authority of provincial People's Committees	6,952,860	8,343,432	7,300,503
Projects which should have been under the licensing authority of Management Boards of IZ and EPZ	2,773,440	3,328,128	2,912,112
Total net benefit	*12,038,463*	*14,314,032*	*12,524,778*



Besides the benefits in terms of reduction in time and money, it is also important reiterate the existence of other benefits like a higher autonomy and freedom to do business, to expand the market an to seize valuable business opportunities. Also, thanks to the reduction in costs, investors can reduce the prices of many goods and services which are believed to be much higher than the averages in many regional countries.

Both, the above figure and table, show that the **net benefits of the regulatory proposal are positive**, which means that when comparing the regulation alternative with the alternative regarding the issuance of no regulation, **the benefits estimated widely exceed its costs.**

G. References

Hanoi (2005). Regulatory Impact Assessment (RIA) of *Unified Enterprise Law & Common Investment Law: With Focus on the Replacement of the Existing Licensing Mechanism with a Registration System Applicable to Foreign Investors.*

Matter of regulation	***General rules for navigation in Miguel Aleman Dam (Valle de Bravo), Mexico State***

Type of regulation *(You can choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	( ) Social regulation (**X**) All indistinctly

Implemented method (s) *(You can choose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can choose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method (**X**)VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis (**X**) Standard Cost Model	( ) Hedonic prices ( ) Defense expenses ( )Method of human capital ( )Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify:

Decision criteria	( )Sensitivity analysis ( ) Immediate Rate of Return (**X**) Other, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal Rate of Return

Case 7. General rules for navigation in Miguel Alemán Dam (Valle de Bravo), Mexico State

A. Introduction

Miguel Alemán Dam (The Dam), also known as Valle de Bravo dam, located in the municipality of the same name in Mexico State, is a nationally owned water infrastructure that is managed by the National Water Commission (CONAGUA, in Spanish). The Dam is part of the Cutzamala System which is the most important hydraulic system in the center of the country and which primary function is the storage of water to supply the demand of approximately 25% of potable water in Mexico City and the metropolitan area of Mexico State. The Dam is the largest and most important infrastructure of the Cutzamala System, as it provides more than a third of the total water of the system.

The Dam is also important for tourism, since nowadays there is approximately 3000 vessels: 1357 of foreign origin, and 1643 Mexicans. Thus, the water activities have been the main attraction of the area for both residents of the state, and for seasonal and weekend vacationers from other states within Mexico.

In this study case we present the appliance of the technical concepts and steps outlined in the guide to evaluate the impact of regulation. To do this we present the problem identified in The Dam, the objectives of the government intervention, the alternatives considered to solve the problem and its impact evaluation by using some of the methods and methodologies explained in the guide, and finally we present the choice of the best alternative according to the evaluation of its effects on society.

B. Definition of the problem

i. Environmental contingency: pollution prevention in The Dam

On May 2012, there was an environmental contingency in the water of The Dam that struck when the Water Commission of Mexico State and the Water System of Mexico City, reported several complaints made to CONAGUA by individuals about the musty odor and taste in the Cutzamala water.

CONAGUA identified The Dam as the origin of these features in the water. The cause of this was the sudden and accelerated proliferation of anabaena[10] and some other algae (marine flora) in The Dam. Authorities found that the accelerated reproduction of algae in The Dam was due to:

a. The low water level of The Dam
b. The increase in the temperature of the water body
c. Unauthorized wastewater discharges
d. The breaking of the cellular chains and membrane of the marine flora due to the navigation of vessels with internal combustion high power engines or at high velocities

Cyanotoxins are harmful cells to human health that live within cyanobacterias or attached to them. Although CONAGUA analysis indicated the absence of cyanotoxins in the water of The Dam, and Mexico does not have any criteria or regulation applicable to

[10] Anabaena algae is a type of algae that commonly breed in fresh water

cyanobacterias and its metabolites for raw and treated water, the Mexican government implemented the measure recommended by OMS that is equal to 1µ / L (micrograms per liter).

Even with these data and since The Dam provides a third of potable water to the Cutzamala System, therefore to a proportion of Mexican population, it is considered that there is a negative externality (market failure) because the inappropriate use by individuals and the water pollution caused either by unauthorized water discharges or by the engine and fuel of the vessels (musty odor and taste) implies negative effects for potable water consumers in Mexico City and the metropolitan area of Mexico State; for this reason the Government decided to intervene immediately with the following actions:

1. Physicochemical and Bacteriological analysis were performed.
2. Activated carbon was applied to remove the algae and its metabolites.
3. Quantity of chlorine applied to The Dam was increased in order to control the musty odor and taste in the potable water.
4. The Government proceeded to the mechanical collection of the algae to reduce its proliferation.
5. Considering that vessels with internal combustion engines can break the cell membrane and accelerate the algae reproduction, the maritime authority, which is the Ministry of Communications and Transports (SCT, in Spanish) through the Merchant Marine General Direction (DGMM, in Spanish), was requested to suspend the navigation of these. **The total restriction for navigation lasted from June 6 to June 22, covering two of the most important weekends for tourism**. The Dam was opened to navigation only to service providers on July 23 and to individual vessels until July 13. Finally, The Dam was opened to navigation for all kind of vessels on August 16, applying some conditions on schedules and navigation areas.

Actions 1 to 4 solved the contingency in the short term at very high cost, which could not be quantified for this analysis. However, the cost of action 5 regarding the restriction for navigation in The Dam, was estimated over 10 million Mexican pesos for losses in tourism.

From the above, the maritime authority identified the problems, causes and solutions of the environmental contingency. These are presented in the table below:

	Problem	Causes	Short term solutions	Long term solutions
ENVIRONMENTAL CONTINGENCY	Uncontrollable growth and reproduction of anabaena and other algae (marine flora) in The Dam	The low water level of The Dam, The increase of the temperature in the water body, and Unauthorized wastewater discharges	Mechanical collection of the algae to reduce its proliferation	Permanently supervise the riverside of The Dam Forbid the unauthorized wastewater discharges, channeling them to the appropriate treatment plants.
	Musty odor and taste in the potable water that generates public concern. Musty odor and taste due to the breaking of the cellular chains and membranes of the marine flora in The Dam.	The use of internal combustion high power engines vessels and/or its use at high velocities.	Actions taken to control the musty taste and odor of the water: Addition of activated carbon. Increase of chlorine in the water of the dam. Restriction to navigation in The Dam in order to prevent that vessels engines increase the breaking of the cellular chains and membranes of the marine flora	Set limits on the power of vessels engine Limit the navigation of high-speed vessels in The Dam Creation of specific zones (where the marine flora proliferates easily) that limit and/or restrict navigation to high-speed vessels. Encourage the use of sailboats.

The previous table shows that the environmental contingency in The Dam is a multifactorial problem in which different institutions (CONAGUA and SCT) and levels of government (federal, state and municipal) are involved to control and prevent the proliferation of marine flora and to keep the levels of quality in the water. In this case, the intervention studied was made by the maritime authority.

ii. The safety of navigation in The Dam

Besides the environmental contingency, the Captaincy of The Dam has registered several maritime accidents and incidents that have concerned the DGMM. The accident rate statistics of The Dam show that between 2010 and 2012, there were **five maritime accidents**: a collision of vessels caused alcohol consumption, a bilge caused by the lack of skills to navigate under the pounding of the waves, a heart attack, a fire, and another one, while trying to disassemble the vessel. These accidents have resulted in **an injured person, four boats damaged, and the loss of six human lives.**

The authority found the following main causes of the mentioned accidents:

- Lack of training and knowledge of the basic rules to navigate.
- Lack of guidelines to navigate and to give a clear delimitation of the areas in which visitants can perform certain activities under surveillance and supervision of the maritime authority.
- Lack of control of foreign vessels navigating in The Dam
- Lack of effective control of the skills to navigate of private vessel owners, including the foreign ones.

- Lack of clear legal provisions that enable the maritime authority to verify that navigators perform water sports in an appropriate physical state.
-

The problems described show the need for government intervention to overcome the government and the market failure. The **government failure** arises from the lack of regulation to comply with the legal attributions of the DGMM in the sense of ensuring the safety of navigation and life at sea as well as preventing marine pollution. The **market failure** arises from the fact that the water, the landscape, tourism, recreation activities and all the goods, services and activities regarding The Dam are goods of public interest, which means that all people can access to and obtain a benefit from its use; but such use generates negative externalities, in terms of the safety of those sailing and in terms of water quality. In this way, government intervention is relevant to promote a greater social welfare.

C. Objectives of the intervention

Among its legal responsibilities SCT, through the DGMM, has to ensure the safety of navigation and life at sea, as well as preventing marine pollution. This forces SCT to take the necessary actions in order to prevent accidents and incidents that affect human life, safety and resources, as well as to prevent environmental pollution. In this sense, the objectives of government intervention are:

- To prevent the incidence of accidents and incidents in The Dam, and, in consequence, the loss of human lives.
- To ensure the safety of navigation.
- To prevent, as far as possible, the pollution in The Dam caused by fuel or by excessive growth of marine flora.

D. Regulatory alternatives

- ***Baseline scenario (issuing no regulation).***

This option implies the no intervention of the maritime authority, which means that the identified problems continue its occurrence .Under this scheme there is no possibility to have control over:

- Foreign vessels
- The technical and practical skills of people who navigating boats in The Dam.
- The security conditions and the appropriate rules for navigation control.
- The prevention of water pollution regarding the use of internal combustion engines and, therefore, the quality of potable water. This means the repetition of a scenario of algae overgrowth and thus the possible closure to navigation in The Dam.

- ***Rules for navigation.***

SCT proposed to issue rules for navigation in The Dam that establish the following:

1. Regularization and registration of the foreign vessels sailing in The Dam. Grace period of six months.
2. Only the vessels under 30 meters length will be permitted to navigation.
3. Only the vessels with internal combustion engine with the following features will be permitted to navigate:
    i. Slow boats with outboard engine with power up to75 H.P., of four-strokes, and
    ii. Fast boat, with stationary engine up to 350H.P.
4. All vessels navigating in The Dam must bring on board a copy of the Rules.
5. All the persons who are part of a crew must have a document identifying them as Mexican Merchant Marine personnel with the necessary technical and practical skills for navigation (Sea Book), or, if it is the case, they must obtain the Lake Card (simpler formality).[11]
6. The Dam will be divided into 4 zones for different types of activities and speed limits:[12]

Zone	Speed limit
ZONE 1 “Precautionary”.	4 knots (7.4 kph)
ZONE 2 “Personal watercraft”	20 knots (37 kph)
ZONE 3 “Ski”	25 knots (46.3 kph)
ZONE 4 “Sailing”	Only sailing boats, slow speed boats or rowing ones

7. Limitation of speed, navigation areas and control of vessels operating under engine power.
8. All vessels must have the flag "O" (man overboard).
9. Restriction to the practice of skiing and rowing at night, as well as control of vessels navigating at the same time, according to the International Regulations for Preventing Collisions at Sea (1972)
10. Navigation restriction to people under the influence of toxic substances.
11. In case a child under 18 and over 6 years old, wants to navigate a boat, parents must present a responsive letter to The Captaincy.

E. International experience

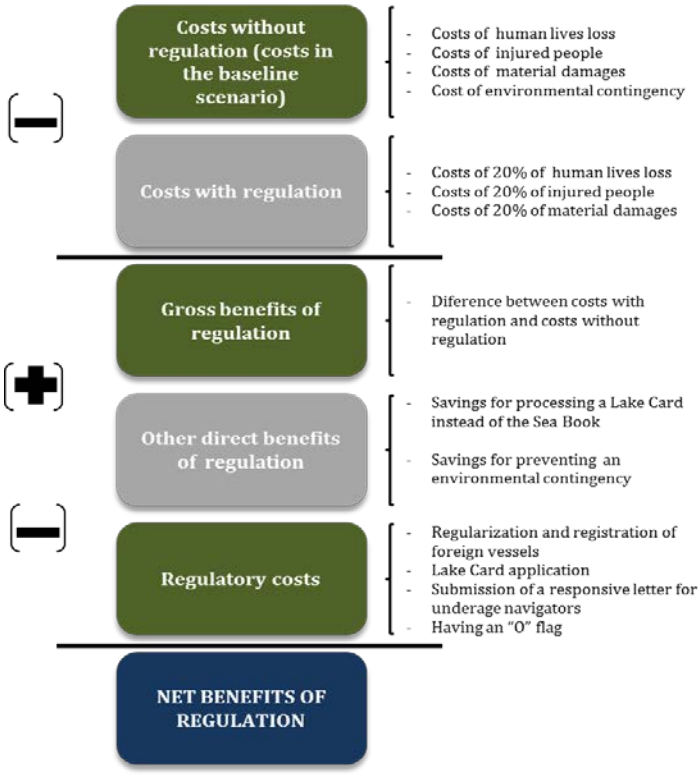
Spain, Argentina and the European Union, have issued general provisions to regulate the use of combustion engines with high pollution potential. In Spain, the Governing Board of the Ebro River Basin approved the emission of navigation rules in reservoirs and rivers,

[11]The Sea Book will be required only for people navigating vessels serving third parties, while the Lake Card can be obtained by those navigating private vessels. The Captaincy has record of 3000vessels; of which350provide services to third parties and2650 are private.

[12] This regulatory action is proposed to overcome the two identified problems. On one hand, there is a division of the nautical activities to increase the safety of users, while on the other hand, the zone restriction is designed according to studies that show the main area of marine flora proliferation, which in the proposed regulation is set as the “sailing” zone in order to avoid the breaking of cellular chains and membrane increasing the risk of water pollution.

prohibiting two-stroke carburation engines. In Argentina, the Patagonian Continental Fishing Rules recommend the general use of certified ultra-low emission engines; it also establishes the mandatory use of low-impact engines on environments such as national parks and reserves. Finally, the EU has proposed to modify the Directive94/25/EC to limit the use of two-stroke carburation engines.

F. Impact evaluation



- ***Baseline scenario (issuing no regulation)***

This alternative implies that the government does not intervene and that the identified problems continue. This involves the following losses or costs per year:

- Two human lives
- 0.33 people injured
- Material damages equivalent to $ 466,666.66 Mexican pesos

Below there is a detailed monetization of the losses mentioned.

a. Cost of human lives loss

In the period covered between 2010 and 20102, the Captaincy has record of 6 persons that died in accidents that involve maritime navigation safety. That is, on average, there is a human loss equivalent to 2 lives per year.

In order to obtain the cost of the loss of a life we use the **Value of Statistical Life methodology** which is implemented through the following equation:

$$Ln\ (VSL) = 2.519 + 1.125 * Ln\ (GDP\ per\ capita) + 0.496 * (Method)$$

Where:

VSL = Value of Statistical Life

GDP = Gross Domestic Product

Method = 1 when using the Willingness to Pay methodology or = 0 when using the Human Capital Method to measure the loss of resources[13]

The Mexican GDP per capita is 9,133 USD; with this information the regulator obtained the following results:

Mexican GDP per capita (dollars)	Ln (GDP per capita)	Ln (VSL)	VSL (dollars)	**VSL (in mexican pesos)[14]**
$ 9,133.00	9.120	12.779	$ 354,550.367	*$4,368,060.527*

Cost of human lives loss = VSL x 2 deaths per year = $8, 736,121.053

b. Costs of injured people

According to the methodology developed by the iRAP, the value of preventing a serious injury is equivalent to 25% of the value of death, which is equivalent to 25% of the **Value of Statistical Life.**

In the period between 2010 and 2012 the Captaincy reported an injured person; therefore, the injured rate per year is 0.33. Then:

Costs of injured persons = (0.25 x VSL) x injured people per year = $360,364.993

c. Costs of material damages

Between 2010 and 2012, three vessels suffered physical damage due to the inappropriate navigation and the lack of technical and practical skills of navigators. The estimation in Mexican pesos of material damages is the following:

[13] In this case, we chose to use the Human Capital Method due to the available data.
[14] The US-MXN exchange rate used is equal to $12.32 pesos per dollar according to The Official Gazette of May 21, 2013.

Vessel	Material damage cost in mexican pesos
Vessel 1	$700,000.00
Vessel 2	$300,000.00
Vessel 3	$400,000.00
Total cost of material damages	*$1,400,000.00*

Costs of material damages = Total cost of the material damages / 3 = $466,666.66

d. Costs of environmental contingency (non-quantifiable)

The actions taken by both, the Government of Mexico State and CONAGUA, had very high costs, however, these are institutions outside the legal attributions of SCT, and therefore the maritime authority does not have the necessary information to quantify them. Nevertheless, is important to mention these costs just to take them into account.

Finally, with all the data obtained we can calculate the COST IN THE BASELINE SCENARIO OR WITHOUT REGULATION:

Concept	Amount in mexican pesos
Costs of human lives loss	$8, 736,121.053
Costs of injured people	$360,364.993
Costs of material damages	$466,666.66
Costs without regulation	*$9,563,152.71*

- **Emission of "*General rules for navigation in Miguel Aleman Dam (Valle de Bravo), Mexico State*"**

This alternative involves the emission of general rules for navigating in The Dam. This will allow the maritime authority to have control over the vessels in The Dam and to monitor the conditions under which water sports are performed. This alternative also seeks for limiting the use of engines with certain physical features to decrease the risk of water pollution.

With the proposed regulation the SCT would achieve the following:

- To have control of the vessels operating in The Dam;
- To increase the safety of navigation and human life;
- To reduce the risk of pollution and impact on water quality of The Dam, and
- To reduce the number of accidents resulting in the loss of human lives and injured people.

Below, each of the costs and benefits needed to assess the impact of this regulatory alternative are distinguished and developed.

a. Costs WITH Regulation

This alternative is intended to prevent accidents and incidents that can result in the loss of human lives, injured people and material damages.

In this section, it is important to consider the existence of factors and conditions outside the SCT attribution that can be directly related to the safety of navigation. Hence it is considered that only 80% of the accidents and losses could be prevented with the emission of the regulatory proposal, while the remaining 20% is not related to the skills of those navigating the vessels in The Dam. Thus, **the costs with regulation are 20% of the costs without regulation**:

COSTS WITHOUT REGULATION		**COSTS WITH REGULATION**	
Concept	**Costs**	**Concept**	**Costs**
Costs of the loss human lives (LHL)	$8, 736,121.053	20% of LHL	$1,747,224.21
Costs of the injured people (IP)	$360,364.993	20% of IP	$72,072.9987
Costs of the material damages (MD)	$466,666.66	20% of MD	$93,333.332
Costs without regulation	*$9,563,152.71*	**Costs with regulation**	*$1,912,630.54*

b. GROSS Benefits of regulation

Gross benefits of the regulation are the result of monetizing the difference between the costs without regulation and the costs with regulation:

Type of scenario	**Total costs**
Without regulation (CNR)	$9,563,152.71
With regulation (CWR)	$1,912,630.54
Gross benefits	*$7,650,522.17*

c. Other direct benefits of regulation

Other direct benefits identified in the regulatory proposal are the following:

1. **Savings for simplifying the formality to prove technical and practical skills of those navigating vessels in The Dam.**

Current regulation requires all navigators, whether providing services to third parties or driving private vessels, to get a Sea Book as proof of their technical and practical skills. However, for purposes of navigation in The Dam, private navigators are only required to obtain the Lake Card.

Get a Sea Book involves cost and time for individuals, therefore, the simplification of this obligation implies a benefit to individuals, as its procedure is easier. In order to get the direct benefit of the latter, we will obtain the costs generated by both formalities, and then, their difference.

The method used to quantify the costs of the Sea Book and the Lake Card was the **Standard Cost Model,** which implies:

1. The identification of the requirements generated for comply with the information obligations (formalities) in the regulation.
2. The identification of the activities to be carried out in order to fulfill each of the requirements.
3. Quantification in Mexican pesos of each requirement and therefore of each formality generated by the regulation
4. Identification of the Individuals that will have to comply with the obligations in order to get the total administrative cost of the formality and thus, of the regulation.

Costs of the Sea Book:

Activity	Stakeholder	Time	Cost per activity
Collection of data and pre-existing information	Individual or Ministry	1 hour	$23.00
Application form for a Sea Book type “C”	Ministry	30 minutes	$11.50
Course of basic safety for those providing touristic services	Individual	----	$240.00
Transportation and assistance to the basic safety course	Individual	13 hours	$575.00
Medical certificate	Individual	3 hours	$24.30
Transportation to government offices and waiting time	Individual	2 hours	$200.00
Fee of the formality	Individual	2 hours	$271.44
		TOTAL	*$1,345.47*

Costs of the Lake Card:

Activity	Stakeholder	Time	Cost per activity
Collection of data and pre-existing information	Individual or Ministry	1 hour	$23.00
Elaboration of a responsive letter when underage want to navigate	Ministry	30 minutes	$11.50
Taking an exam in the Captaincy	Individual	2 hours	$46.00
Transportation to government offices and waiting time	Individual	2 hours	$200.00
		TOTAL	*$280.50*

The Captaincy has record of 2650 private vessels that will have to meet the previous requirements, therefore:

Total cost of the Sea Book = Cost of the Sea Book x No. of vessels = $3,565,495.50
Total cost of the Lake Card = Cost of the lake Card x No. of vessels = 743,325.50

Savings for simplifying the formality to prove technical and practical skills of those navigating vessels in The Dam = *$2,822,170.50*

2. Savings for preventing an environmental contingency

The Ministry of Tourism of Mexico State published that the environmental contingency had a negative impact in both, vessels that provide service to third parties and businesses in the area, for an a amount quantified in $10,000,000.00 Mexican pesos.

The solutions considered to avoid a contingency depend on different institutions and levels of government, so that the actions taken by the SCT will only decrease a percentage of the impact of the contingency. Below is the percentage by which each institution and government agency can directly be responsible of:

Pollution causes	Authorities responsible to take action in prevention	% impact that the Authority can prevent
Unauthorized wastewater discharges	CONAGUA-State-Municipality	35%
The breaking of the cellular chains and membrane of the marine flora due to the navigation of vessels with internal combustion high power engines or at high velocities	*SCT-DGMM*	*35%*
The low level of the water and the increase in the temperature of the water body	Cannot be controlled	30%

In this sense, it is considered that the regulatory proposal can only prevent 35% of the total costs of an environmental contingency:

$$\underline{\textbf{Savings for preventing an environmental contingency}} = \underline{\textbf{\textit{Economic loss due to the contingency x 0.35}}} = \underline{\textbf{\textit{\$3,500,000.00}}}$$

Therefore, the direct benefits of the regulation are:

Benefit	Quantification in mexican pesos
Savings for simplifying the formality to probe technical and practical skills of those navigating vessels in The Dam	$2,822,170.50
Savings for preventing an environmental contingency	$3,500,000.00
Other direct benefits	*$6,322,170.50*

With the information above we can now obtain the Total Gross Benefits by adding the difference between the costs without regulation and the cost with regulation to the other direct benefits:

Concept	Quantification in mexican pesos
Difference between costs without regulation, and costs with regulation	$7,650,522.17

Other direct benefits	$6,322,170.50
Total direct benefits	*$13,972,692.7*

d. Regulatory costs

The regulatory costs are the obligations established in the regulation that generate costs to the Individuals that comply with them. The main regulatory costs identified in the regulatory proposal are:

- Regularization and registration of foreign vessels
- Lake Card Application
- Responsive letter issued by the parents or the guardians of children under 18 and over 6 years old that want to navigate a vessel.
- Have the "O" flag (man overboard) according to the International Code of Signals.

According to the definitions given in the guide and to the nature of the obligations quantified, in this case the costs of compliance with the previous procedures were quantified by using the **Standard Cost Model.**

1. Formality to regularize and register foreign vessels

Activity	Stakeholder	Time	Cost per activity
Collection of data and pre-existing information	Individual or Ministry	1 hour	$23.00
Photocopy of the required documents	Individual	----	$5.00
Painting of the name and registration of the vessel	Individual	----	$100.00
Printing a photo of the vessel to prove that the name and the registration are appropriately painted	Individual	----	$20.00
Document to present the formality	Ministry	30 minutes	$11.50
Transportation to government offices and waiting time	Technician	1 hour	$77.00
		TOTAL	*$236.50*

The Captaincy registers approximately 1357 foreign vessels as an object to be regulated, therefore:

Cost of the formality to regularize and register foreign vessels = ***Unitary cost of the formality x No. of foreign vessels in The Dam*** = ***$320,930.50***

2. Lake Card Application

As we already mentioned, this obligation represents a benefit to individuals as their application process is simpler than that of the Sea Book. The detailed quantification of this benefit was developed in the direct benefits section, hence:

Cost of the Lake Card = Unitary cost of the Lake Card x No. of vessels = $743,325.50

3. If necessary, a responsive letter issued by the parents or guardian of children under 18 and over 6 years old that want to navigate a vessel

When a minor wants to navigate a vessel in The Dam, it is mandatory for the parents or the guardian to notice it to the Captaincy through a responsive letter and a document certifying either the parenting or tutoring. In this case, all the information required is preexisting. Below there is the quantification of the compliance costs that performing this procedure involves.

Activity	Stakeholder	Time	Cost per activity
Responsive letter elaboration	Ministry	30 minutes	$11.50
Photocopy of child's birth certificate	Individual	----	$1.00
Transportation to government offices and waiting time	Technician	1 hour	$77.00
		TOTAL	*$89.50*

Considering that in 2012, 70 underage navigated a vessel, we can obtain the following cost of the responsive letter:

Total cost of a responsive letter issued by the parents or guardian of children under 18 and over 6 years old that want to navigate a vessel = ***Unitary cost of the responsive x No. Of minors navigating per year*** = ***$6,265.00***

4. Have the "O" flag (man overboard) according to the International Code of Signals

The vessels used for skiing and other water sports must have an "O" flag that indicates when there is a man in the water and rescue maneuvers are being performed.

All the vessels that use The Dam can be used for water sports activities. Therefore, we must obtain the cost of the 3000 Mexican and foreign vessels that navigate in The Dam. It is estimated that the raw material of the flag represents the total cost of this requirement.

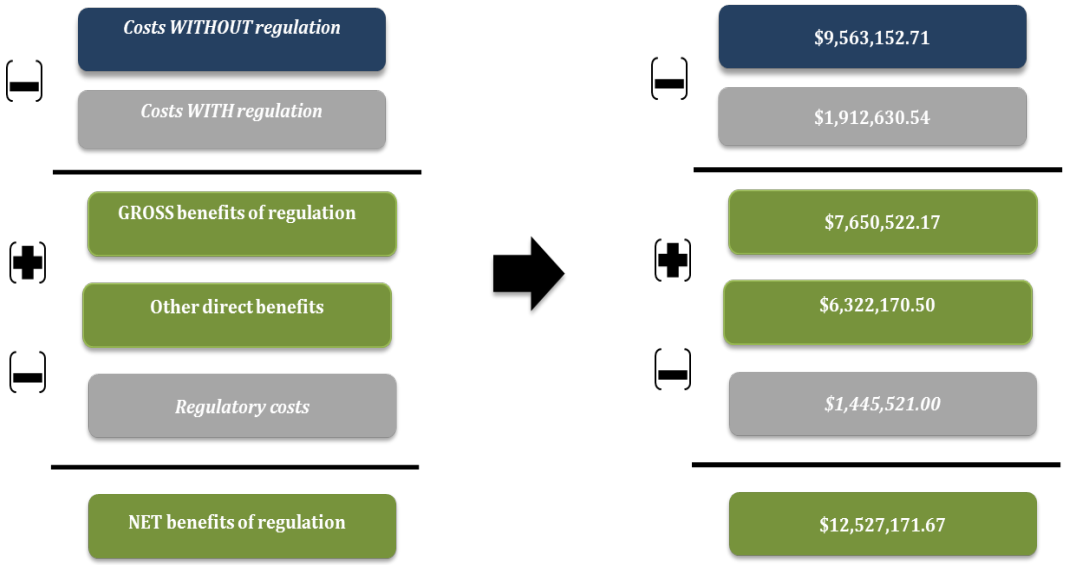
Activity	Stakeholder	Time	Cost per activity
Flag fabric (30cm x 50 cm)	Individual	----	$50.00
"O" fabric (20cm x 20 cm)	Individual	1 hour	$25.00
Edge of the flag	Technician	----	$30.00
Pasting the "O" in the center of the flag	Technician	----	$20.00
		TOTAL	***$125.00***

The regulatory costs of the regulatory proposal are the sum of the administratives costs of each of the previous obligations or formalities:

Formality and/or obligation	Administrative cost
Formality to regularize and register foreign vessels	$320,930.50
Lake Card Application	$743,325.50
Responsive letter issued by the parents or guardian of children under 18 and over 6 years old that want to navigate a vessel	$6,265.00
Have the "O" flag (man overboard) according to the International Code of Signals	$375,000.00
Regulatory costs	*$1,445,521.00*

G. Choosing the best regulatory alternative

In the previous section we obtained the net benefits of regulation as presented below:



The above figure shows that the **net benefits** of regulation are positive; this means that the benefits resulting from comparing the regulatory proposal with the alternative referred to not issue any regulation **widely exceed its costs**.

H. References

COFEMER, Regulatory Impact Assessment (RIA) of the regulatory proposal: http://207.248.177.30/regulaciones/scd_expediente_3.asp?ID=10/0664/031013

Matter of regulation	**Official Mexican Standard PROY-NOM-032-ENER-2013 Maximum consumption limits for equipments and appliances that require standby power. Test methods and labeling**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation	( ) Social regulation
	( ) Administrative regulation	( ) All indistinctly
	(**X**) Two indistinctly, specify: **Economic and Social**	

Implemented method (s) *(You can choose more than one)*	(**X**) CBA	( )CEA
	( ) Multi-criteria analysis	( ) Other, specify:
	( ) Equivalent annual cost	

Implemented methodologies *(You can choose more than one)*	( ) Contingent valuation	( ) Hedonic prices
	( ) Travel cost methodology	( ) Defense expenses
	( ) Cost of illness method	( )Method of human capital
	( )VSL	( )Quality adjusted life years
	( ) Disability adjusted life years	( ) Compensating variation
	( ) Benefit transfer method	( ) Consumer surplus
	( ) Concentration indices	( ) Herfindahl index
	( ) Dominance index	( ) Lerner index
	( ) General equilibrium analysis	( ) Other, specify
	( ) Standard Cost Model	

Decision criteria	( )Sensitivity analysis	( ) Monte Carlo method
	( ) Immediate Rate of Return	( ) Internal Rate of Return
	(**X**) Other, specify: **Benefits greater than costs**	

Case 8. Official Mexican Standard PROY-NOM-032-ENER-2013.Maximum consumption limits for equipment and appliances that require standby power. Test methods and labeling.

A. Introduction

The National Commission for Efficient Energy Use (CONUEE) is a decentralized agency of the Ministry of Energy (SENER) in Mexico, it aims to promote energy efficiency and serve as a technical body on sustainable use of energy. Energy efficiency[15] means all actions leading to an economically viable reduction of quantity of energy required to satisfy energy needs of goods and services demanded by society, ensuring an equal or higher quality level, as well as a decrease in the negative environmental impacts resulting from the generation, distribution and consumption of energy.[16]

According to the National Energy Strategy (ENE) 2013-2027[17] published by SENER, Mexico faces environmental challenges resulting from the generation and use of energy so it is necessary to take effective actions to help to reduce the associated risks of climate change. Specifically, the ENE 2013-2027 considers energy efficiency as a key part of actions to reduce energy consumption and improve the processes of energy production.

In this context, a study published by the National Institute of Ecology (INE) called "*Escenarios de emisiones futuras en el sistema energético Mexicano"*[18], points out that the Mexican energy system depends on 86.42% of fossil fuels (petroleum and petroleum derivatives), and its consumption is predominantly on the oil sector itself, in the electricity sector and large urban centers.

In order to establish concrete goals, the Mexican government is committed to reduce 30% emissions of carbon dioxide (CO_2) compared to the baseline data projected to the 2020, i.e., the government estimated that the emissions would be 960 $MtCO_2$ (million tons of CO_2) in 2020, and then the Mexican government's goal is to reduce that amount by 30%, equivalent to 288 $MtCO_2$[19] and in this way contribute to the mitigation of environmental impacts caused by the use and generation of electricity in the country.

B. Identification of the problem

Nowadays, there is international concern about environmental and energy impacts of the increased consumption of electrical energy used in the household and commercial sectors. This result from the increased use of equipment and the comfort that these equipment and appliances bring in recent years into those sectors, and this trend will continue to grow in terms of the expected technological progress.[20]

According to data from SENER, in the Electricity Sector Outlook 2012-2026,[21] the national electricity consumption for the period 2000-2011 increased from 166,376 to 229,318 GWh (Giga Watts per hour), representing an average annual rate for that period of 2.4%; the

[15].SENER, (2008).
[16].Ibid, Article 3.
[17] SENER (2013a).
[18]Quintanilla Martínez, Juan (s/f).
[19]ENCC (2013).
[20]IIE (2009).
[21] SENER (2013a), pages 97-99.

household sector had the most representative increase of 36,127 to 52,505 GWh implying an increase of 3.5% per year. This, due to the incorporation of new users in some areas of the country, which increased demand for electricity, so according with the study referred, if the energy consumption continues that trend, total energy demand could increase by more than 50% compared to level observed in 2011.

In this document, we will focus on the energy consumption of equipments and appliances, such as televisions, audio players, microwave ovens, among others, which require power to operate, particularly energy expenditure so-called standby power[22] consumption or "vampire" power or "phantom" power consumption, i.e., energy expenditure with those appliances (which include the "on hold" or "standby" and / or allowing the remote on and off) that yet still absorb unused electricity. This consumption has been estimated by the International Energy Agency (IEA) in approximately 10% of total power consumption in the household sector.

A study carried out by the Electric Research Institute (IIE) in Mexico identified that decoders are the equipment that have the highest power consumption in standby mode (16.7 W (Watts) on average), followed by the UPS[23] (11.7 W average) and-set computers (CPU/monitor) (6.3 W average). Next table depicts the average standby mode by some selected equipment and appliances:

Table 1. Equipment and appliances standby power standards

Equipment or appliances	Maximum International standards for standby power (Wh)[/a]	Standby Power (Wh) (Current average consumption)
Digital television adapters	1.00	4.00
Decoders with digital video recording	1.00	26.00
Decoders without digital video recording	1.00 or 2 .00	18.00
Equipment for independent audio playback, separable and non-separable	1.00	2.70
Equipment for reproduction of video or home cinema	1.00	3.80
Scanners	1.00	2.50
Copiers	1.00	2.50
Facsimiles	1.00	2.50
Printers	1.00	2.50
Multifunctionals	1.00	2.50
Conventional microwave ovens	2.00	4.00
Combined microwave ovens	0.05	7.00
Recessed microwaves	1.00	7.00
LED, LCD, PDP, OLED TVs	1.00	3.00

Source: a / Several international studies.

[22]It is the power consumption by equipments and appliances, when connected to the external power supply, while not performing their primary functions or while awaiting instructions to provide full services.
[23]Uninterruptible Power Supply.

The table shows that in Mexico standby power consumption in equipments and appliances exceeds the international levels in standby mode at 5.5 W/h on average. Therefore, the wasted energy in 2012 was calculated at 811 GWh approximately, equivalent to $993 million pesos (mp). By the way, if the power consumption in standby mode with a rising trend continues, then it will reach 11,545 GWh, by 2021 year, equivalent to a loss of $19,030 mp approximately by the electric billing[24].

The absence of standby power maximum consumption standard for electrical equipments and appliances and the lack of consumer information regarding the difference in spending power, it generates that there is a culture of energy saving incentive to manufacturers to innovate technologies that reduce energy consumption in standby mode.

Therefore, the Mexican government decided to intervene to reduce the maximum allowable limits for power consumption in standby mode, to deal with the following **market failures**:

i. The **negative externality** caused by the possible loss of non-renewable natural resources (fossil fuels) that are used as inputs for the production of electricity, and

ii. The **asymmetric information faced by consumers** of electrical appliances and equipments spending by ignoring standby power of appliances they choose to buy. Specifically, we identify a problem of adverse selection, in which consumers have not complete information on standby power mode of equipments and appliances consumption, may affect their buying decision to acquire an asset less efficient than the market average and this would affect the long-term electric billing amount that consumers used to pay.

In summary, the problems described above, result in a **loss of social welfare**.

C. Objectives of the intervention

The Mexican government aims to reduce energy use through energy efficiency of appliances and equipments used in household and commercial sectors, this goal will be achieved by reducing “vampire power consumption" and increasing consumer awareness on energy save.

D. Regulatory alternatives

In order to ensure the government intervention as the best alternative, regulators should identify options to address the problem previously mentioned. Thus, regulators must identify, describe and compare the costs and benefits of all possible alternatives, regulatory and non-regulatory ones, which could serve to solve the situation posed.

- **Baseline scenario (not issuing regulation).**

In this alternative, if energy wasted by equipments and appliances in the household and commercial sectors maintain the upward trend in standby power consumption, it would reach in an average annual loss of $8,532 mp in wasted energy in the 2021 year.

[24] SENER (2013c)

- ***Performance-based regulation. Issuing a Mexican Official Standard***

The Mexican government proposed to establish an Official Mexican Standard (NOM) with the maximum standby power consumption for 14 equipment and appliances in order to avoid wasted power without affecting the welfare offered by the use of such equipment and appliances to the final consumers. The main NOM characteristic is its mandatory instrument role.

Furthermore, in order to improve the availability of information to users at the time they purchase their equipment and appliances, CONUEE made compulsory to place a label on all equipment and appliances with the maximum standby power consumption expected allowed on the equipment that the NOM regulate, and a legend indicating that the equipment or appliance complies with NOM-032-ENER-2013. Specifically CONUEE proposed the following standards:

Table 2.Maximum consumption standby power established in NOM-032

Equipment or appliances	Maximum International standards for standby power (Wh)[/a]	Standby Power (Wh) (Current average consumption)
Digital television adapters	1.00	1.00
Decoders with digital video recording	1.00	15.00
Decoders without digital video recording	1.00 or 2 .00	5.00
Equipment for independent audio playback, separable and non-separable	1.00	2.00
Equipment for reproduction of video or home cinema	1.00	2.00
Scanners	1.00	2.00
Copiers	1.00	2.00
Facsimiles	1.00	2.00
Printers	1.00	2.00
Multifunctionals	1.00	2.00
Conventional microwave ovens	2.00	2.50
Combined microwave ovens	0.05	5.00
Recessed microwaves	1.00	5.00
LED, LCD, PDP, OLED TVs	1.00	1.00

Source: a / Several international studies.

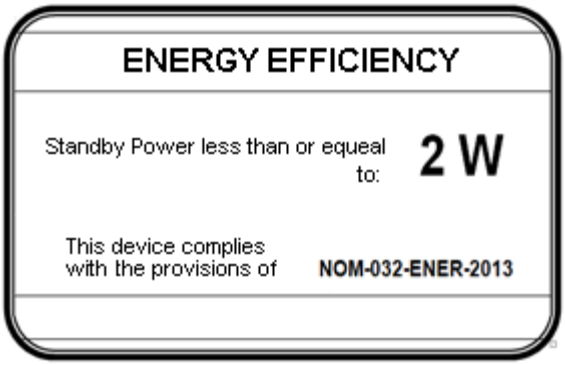
This way, the NOM is intended to reduce to 2.31 W the average standby power consumption of appliances indicated in the table.

- Similarly, the NOM establishes the obligation for producers and importers to placing an energy efficiency label for equipments and appliances that are commercialized in Mexico with the following information:

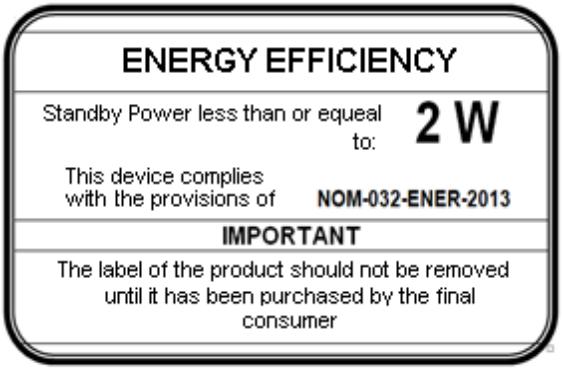
- The name of the label: "**ENERGY EFFICIENCY**", with Arial font, bold and capital letter.
- The legend "**Standby power less than or equal to:**" followed by the value of the electric power in standby mode in watts, set for each equipment or appliance.

- The legend "**This product complies with the provisions of NOM-032-ENER-2013**", with the font Arial, bold.
- In the case that the label is attached to the packaging, either by a rubberized, or failing that, by a cord must include legends "**IMPORTANT**", Arial font, bold and "**The label of the product should not be removed until it has been purchased by the final consumer**" in Arial normal.

Energy efficiency label printed on the package



Energy efficiency label attached to the package



- ***Information campaigns***

This alternative consist in develop information campaigns to enlighten consumers about the standby power consumption and its impact on electric billing, in order to seek to reduce power consumption in equipment and appliances or promote to disconnect them while they are not in function.

This alternative could work if it is used with other measures, but if regulators only implement this alternative alone the goals achieved could be limited, owing to the consumers behavior could be changed in longer term in order to take informed decisions.

E. Impact evaluation

In the previous section we identified three alternatives to address the regulatory proposal: 1) no regulation at issue, 2) use a control scheme based on performance by issuing an Official Mexican Standard and 3) implement an information campaign and awareness of users about standby power consumption. Next, in order to simplify, we focus only on the impact of alternatives 1 and 2:

- ***Baseline scenario (Not issuing regulation)***

General assumptions

All the cases can be reviewed in more detail in the Regulatory Impact Assessment (RIA) made by CONUEE.

- Determine the sales of equipment and appliances subject to the NOM, for the period 2012-2021.
- The average annual growth rate for sales equal to 7.62%.

- The annual growth rate of electricity tariff is estimated at 3.37%.
- The discount rate is 12% annually, according to the established by the Ministry of Finance and Public Credit for investment projects.
- The average hours without the use of equipment and appliances equal to 6,792 hours per year.
- The average cost of power of equipment and appliances in standby mode equal to 4.71W.

With the above data CONUEE calculated, for a time horizon of 10 years, the future costs that the consumers could incur, using the number of sold units of equipment and appliances and their growth rate, the standby power of these items and the number of hours while appliances not performing their primary function, so the results were as follows. Note that annual standby power consumption is expressed in kilo Watts per hour (kWh) and cost (represented by annual turnover) in pesos.

Table 3.Estimatedannual consumption of wasted energy (2012 - 2021)

Year	Number of cumulative sales of appliances/a	Average Standby power by appliance (kW)/b	Average Standby power for all appliances (kW)/b	Cost of kWh (pesos)	Hours unused average year of all appliances	Annual standby power consumption (kWh)	Annual Billing (mp)
2012/e	25,361,084	0.0047112	119,480	1.22	6,792	811,451,383	993
2013	52,654,872	0.0047112	248,065	1.26	6,792	1,684,741,417	2,130
2014	82,028,650	0.0047112	386,450	1.31	6,792	2,624,582,668	3,430
2015	113,640,929	0.0047112	535,380	1.35	6,792	3,636,046,836	4,912
2016	147,662,299	0.0047112	695,660	1.40	6,792	4,724,592,121	6,598
2017	184,276,352	0.0047112	868,154	1.44	6,792	5,896,092,679	8,512
2018	223,680,670	0.0047112	1,053,794	1.49	6,792	7,156,870,322	10,680
2019	266,087,890	0.0047112	1,253,581	1.54	6,792	8,513,728,629	13,133
2020	311,726,856	0.0047112	1,468,593	1.59	6,792	9,973,989,665	15,904
2021	360,843,853	0.0047112	1,699,991	1.65	6,792	11,545,533,488	19,030

Note: e /values estimated from 2012.
a /cumulative sales are considered in order to calculate the total standby power consumption for equipment and appliances that were purchased during the study period.
b /4.7112WkWequals0.0047112
Source: preparation using data from SENER.

However, for comparison in the present of the different amounts that are obtained over time, it is necessary to calculate the present value. CONUEE used a discount rate of 12% and the discount factor calculated using the formula 1/(1+r)t for an assessment 10 years horizon.

$$V_0 = \frac{V_t}{(1+r)^t}$$

Where, V_0 is the present value of an amount at time zero (initial or base)
V_t is the value of a monetary amount in time.
t is the number of periods.
r is the discount rate.
1/ (1+r) t is the discount factor.

In order to calculate the net present value of the amount that consumers will pay between 2012 and 2021, it was the monetary value of the electric billing each of the 10 years comprising the study period, where 2012 year is equal to the period 1 and 2021 year is equal to the period 10. In addition, the CONUEE used an annual discount rate of 12%.

$$V_0 = \frac{995}{(1+0.12)^1} + \frac{2{,}130}{(1+0.12)^2} + \frac{3{,}430}{(1+0.12)^3} + \frac{4{,}912}{(1+0.12)^4} + \frac{6{,}598}{(1+0.12)^5} + \frac{8{,}511}{(1+0.12)^6} + \frac{10{,}679}{(1+0.12)^7} + \frac{13{,}132}{(1+0.12)^8} + \frac{15{,}904}{(1+0.12)^9} + \frac{19{,}030}{(1+0.12)^{10}} = \boxed{38{,}201}$$

With these data it is observed that users can expect to pay up $38,201 mp during the period 2012-2021. The effects of this alternative, involve not reducing standby power consumption of equipments and appliances.

- ***Performance-based regulation. Issuing a Mexican Official Standard***

In the case of the issuance of a NOM, the regulator considered the costs and benefits for final consumers and for manufacturers, thereby addition to the cases listed in Alternative 1 considered the following assumptions.

General assumptions

- The price for labeling is estimated at about $10 pesos.
- Laboratory tests costs equal to $15,000 pesos per household equipments and appliances.
- Certification costs equal to $7,500 pesos per household equipments and appliances.
- 150 families of appliances and equipments to be certified.
- Reduction in average electrical power equipments and appliances in standby mode from 4.71W to 2.31W.

a. Benefits

Derived from the cases mentioned above we have the following:

Table 4. Estimation of annual consumption of wasted power (2012 - 2021)

Year	Number of cumulative sales of appliances[a]	Average Standby power by appliance (kW)/[b]	Average Standby power for all appliances (kW)/[b]	Cost of kWh (pesos)	Hours unused average year of all appliances	Annual standby power consumption (kWh)	Annual Billing (mp)
2012[e]	25,361,084	0.00231	58,532	1.22	6,792	397,524,271	486
2013	52,654,872	0.00231	121,525	1.26	6,792	825,342,857	1,044
2014	82,028,650	0.00231	189,319	1.31	6,792	1,285,764,413	1,680
2015	113,640,929	0.00231	262,279	1.35	6,792	1,781,273,526	2,407
2016	147,662,299	0.00231	340,799	1.40	6,792	2,314,544,132	3,232
2017	184,276,352	0.00231	425,303	1.44	6,792	2,888,453,937	4,170
2018	223,680,670	0.00231	516,246	1.49	6,792	3,506,099,952	5,232

2019	266,087,890	0.00231	614,120	1.54	6,792	4,170,815,202	6,434
2020	311,726,856	0.00231	719,453	1.59	6,792	4,886,186,714	7,791
2021	360,843,853	0.00231	832,813	1.65	6,792	5,656,074,874	9,323

Source: Preparation using data from SENER.

In order to compare in the present amounts obtained in different periods it is necessary to use the net present value formula using the discount factor 1/(1+r)t. Thus the annual electric billing for the period reviewed in net present value is $18,714 mp.

$$V_0 = \frac{486}{(1+0.12)^1} + \frac{1{,}043}{(1+0.12)^2} + \frac{1{,}680}{(1+0.12)^3} + \frac{2{,}406}{(1+0.12)^4} + \frac{3{,}232}{(1+0.12)^5} + \frac{4{,}169}{(1+0.12)^6} + \frac{5{,}232}{(1+0.12)^7} + \frac{6{,}433}{(1+0.12)^8} + \frac{7{,}791}{(1+0.12)^9} + \frac{9{,}322}{(1+0.12)^{10}} = \boxed{18{,}714}$$

While wasted energy in standby mode is $18,714mp, as compared to the energy wasted in case of not issuing any regulation is possible to see a profit of $19,486mp, because this represents the decrease in electric billing that final consumers will gain with the establishment of maximum standby power consumption of equipments and appliances regulated.

$$\text{Gross benefit} = \textit{Unregulated costs} - \textit{Regulation costs}\ (NOM)$$

$$\text{Gross benefit} = 38{,}201{,}560{,}109 - 18{,}714{,}673{,}039 = \boxed{19{,}486{,}887{,}069}$$

b. Regulatory costs

To comply with the proposed regulation, manufacturers must cover the labeling, laboratory tests and certification costs necessary to comply with the regulation alternative. Thus CONUEE assume an increase of 5.15% in the prices of labeling, certification and laboratory tests for equipments and appliances, and the costs generated by the last two concepts were assumed equal to $7,500 and $15,000 pesos respectively.

The following table depicts the unit costs of labeling, certification and laboratory tests that were multiplied by total units sold of equipments and appliances, so we get the following total costs:

Table 5.Unit and total costs for the implementation of the regulatory proposal

Year	Label (pesos)	Certification (pesos)	Laboratory tests (pesos)	Number of sales of equipments and appliances (unit)	Total costs (mp)
2012	10.76	0.05	0.10	25,361,084	277
2013	11.32	0.05	0.11	27,293,788	313
2014	11.90	0.06	0.11	29,373,778	354
2015	12.51	0.06	0.12	31,612,279	401
2016	13.16	0.06	0.12	34,021,371	454
2017	13.83	0.06	0.13	36,614,053	514
2018	14.55	0.07	0.14	39,404,317	581
2019	15.30	0.07	0.14	42,407,220	658

2020	16.08	0.08	0.15	45,638,967	744
2021	16.91	0.08	0.16	49,116,996	842

Source: prepared using data from SENER.

Moreover, in order to compare the results of various time periods we use the present value formula for a period of 10 years. The results are shown below:

$$V_0 = \frac{276}{(1+0.12)^1} + \frac{313}{(1+0.12)^2} + \frac{354}{(1+0.12)^3} + \frac{401}{(1+0.12)^4} + \frac{453}{(1+0.12)^5} + \frac{513}{(1+0.12)^6} + \frac{581}{(1+0.12)^7} + \frac{657}{(1+0.12)^8} + \frac{744}{(1+0.12)^9} + \frac{842}{(1+0.12)^{10}} = \boxed{2{,}589}$$

If the calculation is performed for each of the components of the costs that the manufactures incur, the regulatory costs of the NOM are equivalent to $2,589 mp, corresponding to the labeling costs ($2,554 mp), certification costs ($12mp) and laboratory tests costs ($23mp).

F. Choosing the best regulatory alternative

Based on the costs and benefits of the two alternatives previously analyzed, we can determine the best alternative to issue the regulation using the benefits superior to costs criteria, which consist simply to compare the costs and benefits of both proposals and next to choose that one which produces the greatest net benefits to society.

Table 6. Costs and benefits of each alternative.

	Alternative 2 (mp)
Unregulated costs (Alternative 1 costs)	38,201
Regulation costs	18,714
Gross benefits	19,487
Regulation costs of the NOM	2,589
Net Benefits	*16,898*

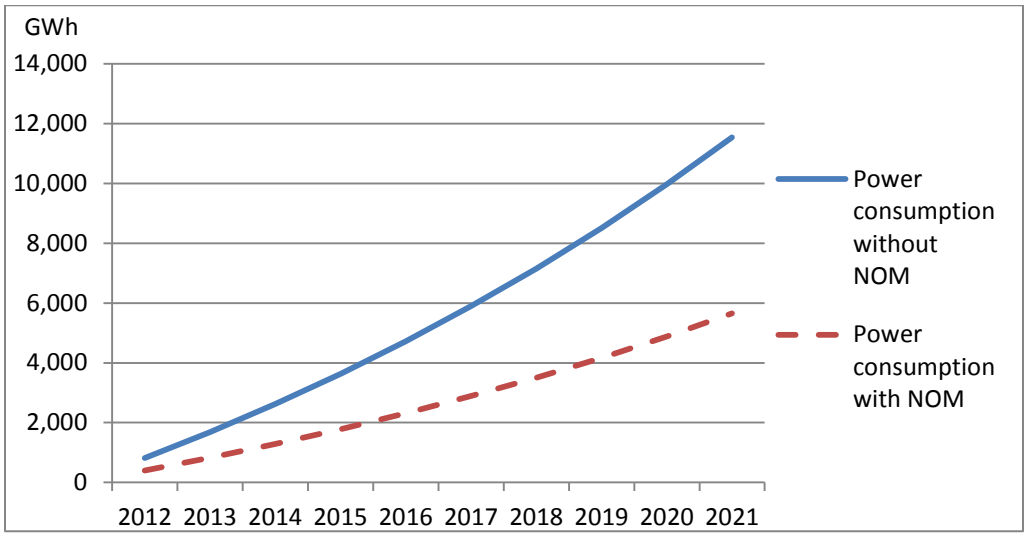
Source: Own elaboration.

On one hand, it appears that the costs of Alternative 1(not issued any regulations) consist of an increase in the electric billing of $38,201 mp, however although here are benefits of this proposal, for example, to avoid the costs of implementing the regulation, the regulator does not have data that can bring such benefits.

On the other hand, with the implementation of the NOM, users will benefit from a reduction in their electric billing about $ 19,487 mp; in the first 10 years of implementation of the NOM, the costs of the proposal will be approximately $2,589 mp consisting in the labeling, certification and laboratory tests costs that manufacturers transfer to users by increasing the price of final goods.

Also, there is a reduction in the power consumption for equipments and appliances in standby mode, which could reach 5,657 GWh in the first 10 years of implementation of the NOM, which highlights the benefits of the regulatory proposal.

Graph 1.Power consumption in standby mode of alternatives 1 and 2



Source: Own elaboration based on SENER data.

G. Final remarks

Other necessary elements to strength regulatory impact analysis, consist in presenting information on long-term structural costs, i.e. costs that manufactures will have to pay to sustain technology to improve the energy efficiency of equipments and appliances, and manufacturers may incur higher costs to change their production line or remove equipment stock lines that cannot meet the maximum consumption standby power or the labeling requirements set out in the regulatory proposal, this type of costs is also relevant to the regulatory impact assessment.

During the public consultation of the regulatory proposal, comments were received from the following companies:

1. Hewlett Packard (HP) Mexico
2. Lexmark International in Mexico
3. Brother International in Mexico
4. The Consumer Electronics Associations

Their comments refer mainly, among others, to strengthen the Cost-Benefit Analysis with recent data.

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I. Problems the regulator faced when evaluating the regulatory impact

The problems CONUEE could face to estimate structural costs of the regulatory proposal, consist mainly in the difficulty to obtain this information from manufacturers because it is relevant information on its structure costs.

Also CONUEE noted that to build a hypothetical example that compares the costs incurred by manufacturers to use current technology standards and additional costs would have to be done by the use of new technology that will allow comply with the maximum energy efficiency of equipments and appliances in standby mode, it would be difficult since it involves creating unique assumptions for the case of the Mexican market compared to current standards and additional costs would have to be done by the use of new technology for equipments and appliances in standby mode.

Matter of regulation	**Official Mexican Standard. NOM-005-SCFI-2005. Measuring instruments-System metering and dispensing petrol and other liquid fuels-Specifications, test methods and verification procedures**	
Type of Regulation *(Choose the preponderant one)*	(**X**) Economical R. ( ) Administrative R. ( ) Two of them indistinctly, specify:	( ) Social R. ( ) All of them indistinctly
Applied method(s) *(You can choose more than one)*	(**X**) CBA ( ) A. Multicriteria ( ) Equivalent yearly cost	( )ACE ( ) Another, specify
Applied methodology *(You can choose more than one)*	( ) Contingent assessment ( ) Transportation cost ( ) Sickness cost ( ) VSL ( ) AVAD ( ) Benefits transfer ( ) Concentration Ratio ( ) Dominance index ( ) General equilibrium analysis ( ) Measurements of administrative burdens	( ) Hedonic Prices ( ) Defense expenses ( ) Human Capital Method ( )AVAC ( ) Compensatory Variation ( ) Consumer Exceeds ( ) Herfindahl Index ( ) Lerner Index ( ) Another, specify
Decision Criteria	( ) Sensitivity Analysis ( ) Immediate Yield Rate (**X**) Another, specify**: Benefits greater than costs**	( ) Monte Carlo's Method ( ) Internal Rate of Return

Case 9. Official Mexican Technical Standard. NOM-005-SCFI-2005. Measuring instruments-System metering and dispensing petrol and other liquid fuels-Specifications, test methods and verification Procedures

A. Introduction

In Mexico, the fuel and lubricants' distribution and retail marketing, is done exclusively through what has been named PEMEX Franchise, which can be acquired by Mexican individuals and enterprises.

Under this business model, nowadays (2013) there are 10,564 stations in our country, with sales for about 793 thousand barrels per day, from which 92.9% is "Pemex Magna" gasoline and 7.1% is "Pemex Premium" gasoline. Diesel's sales are about 332 thousand barrels per day[25].

To give the retail marketing service, franchises use machines called dispensaries, which are composed by mechanical, electronic and informatics elements, which let them obtain more exact measurements.

In order to assure the effective dispatch of liquid fuel, Mexican Government has made several efforts.

- On May 31st, 2006, the "***Reliability Coordination Agreement Dispensary"***[26], (Coordination Agreement) among the Federal Government and the dispensaries' producers, in which the producers are committed to "*produce, distribute and sell new and reliable dispensaries*" in order to accomplish the NOM-005-SCFI-2005[27], and include any of the following devices: encapsulated chip or system's main card embedded with software and encryption algorithm MD5 to 128 bits. As well as to include the following control devices or their equivalent: audit schemes tracks and events binnacle that could let obtain the non-altered and non-erasable information from all the accesses to the dispensary's electronic module, particularly the calibration, configuration and flow's measurement.

- In addition to that, on June 26th, 2006, the Federal Government published in the Official Journal of the Federation the ***"Decree that grants fiscal incentives to taxpayers that acquire and install gasoline dispensaries in establishments open to people in general" I"***[28] (Decree), which had a life of 6 months and granted a fiscal incentive to taxpayers who transfer gasoline or diesel for automotive combustion in establishments open to people in general. The incentive consisted in permitting the crediting of the income tax they were obliged to pay or the one retained by others; as well as the tax assets or the value added tax; equivalent to the 70% of the original amount of the investment in dispensaries that could accomplish with the NOM-005-SCFI-2005 and with the security conditions indicated in the Coordination Agreement.

[25] Consulted in the following web page: http://www.ref.pemex.com/index.cfm?action=content&sectionID=11&catID=19
[26] This action corresponds to an alternative of **Quasi-regulation** (see Chapter 1 of the Guide).
[27] Official Mexican Norm, NOM-005-SCFI-2005 Measuring instruments-System metering and dispensing petrol and other liquid fuels-Specifications, test methods and verification, so that the verifying authority (PROFECO) can have reliable registers about the accesses -face and remote- to the electronic, computer program and configuration of dispensaries.

[28] This action corresponds to an alternative about **Market Instruments** through economic incentives, specifically subsidies (see Chapter 1 of the Guide).

The total amount of the incentive that could be credited, in any way could exceed $77,000.00 for each dispensary that taxpayers acquire and install in their establishments.

Besides, the Decree granted another fiscal incentive consisting on crediting of the income tax they were obliged to pay or the one retained by others; as well as the tax assets or the value added tax, the 30% of the investment in new dispensaries, for transferring the old dispensaries to transform them in junk and effectively those can be transform in scrap in a term of no more than 6 months. The total amount of the incentive, in any case could exceed $33,000.00 for each dispensary that taxpayers acquire and install in their establishments.

B. Identification of the problem

Since 2004, previous to the actions taken by the Coordination Agreement and the Decree, Mexican authorities had identified that 90% of the service stations did not give full liters to consumers, in average the missing fuel was the equivalent to 5%, that is, 10 times above the tolerance level. According to the estimation, the losses are equivalent to an amount from 14 to 20 thousand million pesos per year.

On the other hand, a survey done in 2005 by the Federal Prosecutor Consumer, demonstrated that the 86% of the consumers didn't trust gas stations, by that time there was a total of 7,200 PEMEX franchises.

With the two actions taken by the government in 2006, the 43% of the dispensaries of liquid fuels were substituted. So, with the technical information given by the National Metrology Center and the producers of dispensaries, is possible to calculate that **26,213 (57%)** out of **46,160** existent dispensaries were missing reliability attachments (encapsulated chip or system's main card or audit schemes tracks and events binnacle). Besides that, the problem has grown; recently it has been found the disturbance in the computer or the counter of the dispensaries, which permits the execution of different directions so that they dispatch a volume of fuel that does not correspond to the paid amount, action that affects consumer's welfare.

A proof of that were the immobilizations of hosepipes in gas stations in our country, done by the Federal Prosecutor Consumer, where they found substitutions and disturbances in the electronic system of the dispensaries (hardware and software) in 19% of the 10,048 instruments in 2009, while in 2010 there were 13.2% of 7,518.
Some causes of the stated problem, are:

1. The lack of **reliability attachments in the 57% of the dispensaries in our country**;

2. The lack of control in the substitution of the electronic components in the fuel's dispensaries, and,

3. The inexistence of a non-altered and non-erasable inventory system, that makes evident -the face and remote- accesses to the electronic, software and configuration in the dispensary; which would have to be limited, by the authority and the producer, only to activities like changing the price, adjusts, maintenance and repairs.

In this sense, we can identify the existence of a **market failure**, in the form of an **information asymmetry**, which implies that the product's seller –the franchisee- knows better the quality of the merchandise that is offering to the consumer, what puts him in disadvantage. This information asymmetry provokes a **moral hazard** problem, since the franchisee can alter the dispensary's software or hardware with the purpose of not dispatching complete liters and defrauding the consumer. That happens because is not likely that the consumer takes notice and prove the fraud.

Because of this situation, Mexican government has had the need to continue intervening with the purpose of assuring the welfare of consumers.

C. Objective of the intervention

The general objective of government's intervention is to guarantee that franchisees dispatch complete liters, avoiding the substitution and disturbance of the electronic original components that dispensaries' software has.

D. Regulatory alternatives

The Mexican state, through the Ministry of Economy analyzed and assessed the following alternatives:

- ***Baseline scenario (not issuing regulation).***

This option considers the possibility of letting the problem's solution to the good will of franchisees so as not to defraud consumers, as well as an excessive verification by the consumer protection authority. Nevertheless, from 2006 to 2012, the franchisees' behavior hasn't been modified substantially; either by the Coordination Agreement, or by the fiscal incentives Decree.

So, not emitting a **specific regulation** will continue to affect the rights and welfare of consumers, through illegal and irregular actions, with any disturbance to dispensaries.

- ***Agreements' subscription.***

With this option, it isn't warrantied the permanent accomplishment of the contracted obligations on its own initiative, because of the temporary nature and the lack of universal application of agreements; since *these ones only obliged their signers not new suppliers of dispensaries to gas stations, as long as it's convenient to their interests*.

Likely, it's identified that the Agreement partially attends the problem, because even when dispensaries are made with technical characteristics included in the 2006 Coordination Agreement, and that the same producers reveal metrological adjustments and changes before the authorized sale, that evidence cannot be used to punish those practices in the gas stations; because the reliability attachments weren't included in the NOM-005-SCFI-2005 so as to be subject of verification by the authority.

- ***The emission of a Mexican Standard.***

A Mexican Standard is a technical standard emitted by privates that aims at taking care of quality in products, processes or services, among others. It is voluntary executed. That's

why, the Ministry of Economy did not consider feasible to enforce obliged dispositions through a voluntary instrument.

- ***Modification of the Official Mexican Standard NOM-005-SCFI-2005***

The analysis of the previous alternatives has as a result that these ones wouldn't accomplish solving the given problem; consequently, the modification of the NOM-005-SCFI-2005, through the regulatory project called NOM-005-SCFI-2010 was proposed.

The modification would have as an objective to make obligatory the reliability attachments in dispensaries, so they could generate a legal base that could be verified by the authority regarding its accomplishment and to prevent, or punish in the case of manipulating the dispensaries.

The project of modification is preventive, that is, it avoids risks about the commercial fuel transactions, besides that, it aims to be coherent with national law and with international regulations in metrology, particularly, because **the technology** with which dispensaries work improve precision, the facility of use and the certainty in dispensaries' measurements, but it doesn't save they integrity in the measurements' registers and the dispatches that are done.

The purpose of this explicit regulation is to establish the specifications, proof methods and verification procedures that, will be applied to different systems to measure and dispatch gasoline and other liquid fuels that are marketed and used in commercial transactions, in order to guarantee the dispensaries' integrity and avoid that substation and disturbance in the original electronic components of those systems can result in any damage to the consumer's economy.

E. Impact evaluation

The impact's evaluation was done through the cost-benefit analysis. To do this, it was necessary to identify the following:

a. Direct benefits of the regulatory proposal[29]

- Saving resources in terms of the loss of consumers' welfare by avoiding fraud by franchisees in not dispatching complete liters.

To calculate the benefits, the Ministry of Economy used the average value of ***paid fuel and not delivered,*** the way it is explained in the following chart:

[29] It is important to mention that direct benefits of the regulatory action are equivalent to the cost of the alternative of not emitting any regulation.

Analysis entries	2008	2009	2010
Amount of gas sold per station. **(mop: millions of pesos)**	$44.99	$41.42	$46.20
Gas stations that deliver incomplete liters.	602	321	332
Amount of sales from gas stations that deliver incomplete liters **(mop).**	$27,081.55	$13,296.89	$15,339.01
Average of the maximum missing detected per gas station, deducting the maximum permissible error.	4.04%	2.79%	2.62%
Yearly amount of paid fuel and not delivered (mop).	$1,094.09	$370.98	$401.88
Yearly average of paid fuel and not delivered.	622.32 millions of pesos per year		

Together with the above, the following assumptions were used:

1. A horizon of 5-year-evaluation, since it is the period in which the norm is valid, before it gets to its revising period, so that in its case it is modified, ratified or canceled.
2. A rate of discount of 12% for being this the social rate of discount calculated by Mexican government for social projects.
3. In a verifying exercise the gas stations that don't sell complete liters were identified, the same way, the average percentage of damage to consumers' economy was obtained, deducting the maximum permissible error.
4. From the gas stations that dispatch incomplete liters we obtained the amount of its yearly sales and applied the average percentage of the maximum missing detected.
5. In this way, using the formula of Net Present Value, we have that the regulation's benefits are estimated in **$2,243.32** million of pesos.

b. Direct costs of the regulatory proposal

- Adjustment's cost or dispensaries' replacement that miss reliability attachments (26,213 dispensaries).

The regulation's costs are calculated in terms of the unit cost of enabling or, if the case, substituting the dispensary, multiplied by the number that would have to enable or replace. In these terms, the estimated cost is mentioned below:

Type of action/ Costs	Unit cost (pesos)	Number of units	Total Cost (mop)
Enable	$14,871.93	16,211	241.08
Replace	$129,948.11	10,002	1,299.74
Total		*26,213*	***$1,540.83***

The costs of regulation for the year 1 were deducted from time zero, with a rate of 12%, as well as the benefits, resulting in average costs of $1,375.74 million pesos.

F. Choosing the best regulatory alternative

The analysis presented by the Ministry of Economy leads to the conclusion that the proposal would generate the following accomplishment's costs and benefits:

Cost-Benefit Analysis (mop)	
Net Present Value of the Costs	$1,375.74
Net Present Value of the Benefits	$2,243.32
Benefit/Cost (BCR)	*1.63*
The benefit is 63% superior tan the cost.	

G. References

COFEMER, Regulatory Impact Assessment (RIA) of the regulatory proposal: http://207.248.177.30/regulaciones/scd_expediente_3.asp?ID=03/1794/240211

PEMEX Franchise web page : http://www.ref.pemex.com/index.cfm?action=content&sectionID=11&catID=222

H. Problems the regulator faced when evaluating the regulatory impact.

The initial calculus of the damage to the consumers' welfare was severely criticized by citizens and business chambers, since they found methodological failures to calculate it. This originated that COFEMER asked for more precision in the information and the followed methodology in order to adjust the cost-benefit analysis.

Matter of regulation	**Regulatory Proposal on Consolidation of Local Service Areas**

Type of regulation *(Choose the preponderant one)*	(**X**) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	( ) Social regulation ( ) All indistinctly

Implemented method (s) *(You can choose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	( )CEA ( ) Other, specify:

Implemented methodologies *(You can choose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method ( )VSL ( ) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration indices ( ) Dominance index ( ) General equilibrium analysis ( ) Standard Cost Model	( ) Hedonic prices ( ) Defense expenses ( )Method of human capital ( )Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify: <u>Estimation of demand</u>

Decision criteria	(**X**)Sensitivity analysis ( ) Immediate Rate of Return ( ) Other, specify:	( ) Monte Carlo method ( ) Internal Rate of Return

Case 10. Resolution by which the Plenary Meeting of the Federal Commission of Telecommunications modifies the "Administrative Resolution which establishes the guideline for carrying out the consolidation of existing Central Groups of Local Service into Local Service Areas, as well as the respective Calendar for Consolidation," published on November 30th 1998 in the Official Journal of the Federation and the "Fundamental Technical Numbering Plan" published on 21st June 1996 in the Official Journal of the Federation.[30]

A. Introduction.

The Local Service Areas Background in Mexico

The 1990-2002 telecommunications regulatory reform

In recent years, the telecommunications sector in Mexico has experienced major reforms in its regulatory framework, evolving from an inefficient State monopoly —providing a small variety of services such as local calls, long distance and international calls— into a more competitive market, with several companies and a wide range of telecommunication services (such as calling cards, caller ID, voice mail, calls in waiting, data transfer, online banking services, video on demand, video conferencing and internet services).

In the 1980's, the collapse of the macroeconomic environment in Mexico triggered major changes in the economic model of the country, making it one of the first Latin American nations to adopt market principles as a key element for economic development. Under this new economic model, the macroeconomic stabilization policies were supported by trade liberalization and privatization.

In 1990 the first step happened towards the reform in the telecommunication sector, which consisted in the privatization of the state-owned monopoly, *Teléfonos de Mexico* (Telmex), through the granting of a modified concession, which allowed exclusive access to the national and international long distance markets until 1996. **Theoretically, other companies could enter the local markets, but the maintenance of domestic long distance monopoly was allowed so that Telmex might achieve their goals of expanding the network and readjustment of the structure of their rates.**[31]

In this context, in the year 1995 the Federal Telecommunications Law (FTL) was published to promote market elements, spectrum allocation and establish an interconnection framework for existing public telephone new entrants. The main objective of the law was to promote competition among recent telecommunication providers through improved services, diversity, quality and better prices.

Starting in 1996, the Mexican government took measures **to open up markets to competition, in particular, in the domestic and international long distance**

[30] The Resolution for the Consolidation of the Local Service Areas (in Spanish, ASL) was published on july 1st 2013 in theOfficial Journal of the Federation, and can be seen in the following link:
http://www.dof.gob.mx/nota_detalle.php?codigo=5304635&fecha=01/07/2013

[31] En In this context, the fixed line penetration in accordance with data from the Cofetel was only approximately 9.8 lines per 100 inhabitants in 1997 and 10.3 per 100 inhabitants in 1998. On the other hand, the average rate in the member countries of the OECD for those years was around 50 lines per 100 inhabitants.

services.[32] The entry of new participants to the market led to a price competition in the long distance service, declining market share of Telmex. In long distance, the new entrants have taken nearly 30% of the market.[33]

In 1996 the fixed telephony market consisted of both the competitive services (long distance) and the non-competitive services (local telephony). Although it was already initiating the competition in the long distance services, the infrastructure of the new entrants was incipient and depended on the capacity of Telmex, both for its access to the final consumer as to provide long distance services on some routes. In spite of the problems, the regulatory regime allowed rapid development of competition in long distance service.[34]

On June 21th, 1996, the Cofetel[35] issued the Fundamental Technical Numbering Plan (in Spanish, PTFN) according to the guidelines of the Resolution on the public long distance networks interconnection Plan[36], which aimed to achieve greater numerical resources, i.e. the possibility of more combinations of telephone numbers for the country under the increasing growth of telecommunication services in those years and the recent opening to competition of the basic service of long distance and to accommodate the new entrants to the market.[37]

The PTFN allowed to rearrange the telephone numbering granted to the date, to harmonize the criteria for the allocation of key long-distance and attend to the international recommendations on the subject of telecommunications of the OECD, **for which there was established an extension of the length of the national number of 10 digits, which, in accordance with the Cofetel would allow to satisfy an expectation of average annual growth of 10% of local numbers demand for the next 40 years**, and as populations were requiring greater numbering would extend the length of local numbers from these populations until reaching the limit set by the PTFN.

For the second half of 1997, started a process of integration of the Central Local Service[38] scheme toward the Local Service Areas (In Spanish, ASL[39]) through the publication in the DOF of the Rules for the Local Service (RSL) that allowed to reorder territorially the telephone numbering of the country and regulate the installation, operation and exploitation of public telecommunications networks of the authorized concessionaries to provide the local fixed or mobile services, and establish the guidelines applicable to the

[32] New participants in long distance included companies backed by prominent USA phone companies such as MCI and A&T http://www.verizonenterprise.com/mci/ and http://www.att.com/

[33] The granting of diverse authorizations for cellular services and the allocation of frequencies across(through) auctions of electromagnetic spectrum, promoted competition in wireless service markets.

[34] In March of 1998, the Federal Competition Commission (CFC) concluded that Telmex possessed substantial market power in five major markets: local telephony, interconnection services, domestic long distance, long distance and international long distance reselling, derived from that, Telmex is practically the owner of virtually all local public networks and provides local services and interconnection.

[35] Federal Commission of Telecommunications.

[36] Published in the DOF on July 1, 1994 this Resolution on the Interconnection Plan established basic guidelines for interconnection that forced TELMEX/TELNOR to interconnect telecommunications networks operators of long distance to his central focus public long distance traffic in any city it was requested.

[37] The numeric resource began to show signs of saturation in the city of Mexico and its suburbs, where the occupation of the numbering is close to 50 percent. Similar situations present the codes of special services and the prefixes of access of long distance in which the occupation reaches 80 and 70 per cent respectively. The previous thing motivated the Federal Government to look for alternatives that were allowing a more efficient use of the numerical resources.

[38] The Rules for the Local Service define the Central Local Service Groups as a set of local stations within which is pursuing public traffic switched without dialing a prefix of access to the long distance service

[39] A Local service area is defined as a geographical delimitation which provides local service between users located at any point within it.

interconnection and interoperability between concessionaries of the local service or with authorized concessionaries to provide long distance services.

Also, the Rules defined a schedule of gradual consolidation for the central service groups and, at the end of 1998, the Cofetel issued the *"Administrative Resolution which establishes the guideline for carrying out the consolidation of existing Central Groups of Local Service into Local Service Areas, as well as the respective Calendar for Consolidation"*. As a result of the consolidation realized in the years (1998-2002), there are currently (up to 2013), 397 ASL .

- The ASL approach seeks: minimizing the costs of integration to prevent a rise in rates for local service, trying to respect the existing phone network topology.
- Include complete municipalities within a same ASL
- Not to include two or more cities in a same ASL that already had long distance services.
- At least 1,500 lines for each new ASL in operation.
- Maintain the regions of frequency allocation.
- Consider specific requests from users and regional Governments of consolidation of local service groups.

With the transition to Local Service Areas, Cofetel estimated an objective to reduce long distance destinations in 72 %, increase the average number of lines per local area from 6,147 to 22,167 providing legal certainty to the concessionaries in the local and long distance service to establish better incentives to invest in this service due to the increase of the geographical coverage.

Table 1. Background of the current definition of ASL

Year	Legal framework	Objetive
1996	Fundamental Technical Numbering Plan (PTFN), published in the DOF on June 21, 1996	The SCT set the premises for proper use and administration associated with signs and numbers of public telecommunications networks, in order to achieve efficient interconnection and interoperability of such networks through an efficient, fair, equitable and non-discriminatory allocation.
1997	Transitory sixth Rule of the Rules of the Local Service (RSL) published in the DOF on 23 October 1997	The consolidation of the Local Central Groups into Local Service Areas (ASL) − Period: 5 years − No more tan 485 ASL − The ASL may not have less than 1,500 lines
1998	Administrative Resolution which establishes the guideline for carrying out the consolidation of existing Central Groups of Local Service into Local Service Areas, as well as the respective Calendar for Consolidation, published in the DOF on November 30, 1998	The Resolution of consolidation complies with the RSL: − Defines the Local Service Areas. − Consolidating the groups existing in ASL local service stations: went from 1,464 to 397 ASL based on municipal geographic groupings − 3 years process (1999-2000)

Source: SCT, 2009

Finally, for the period of 2002-2007 the Cofetel received numerous requests from citizens, concessionaries, State and Municipal authorities to integrate even further the ASL

configuration in México. It should be noted that the Cofetel subsequently sought to carry out more consolidations in the country, however faced various litigations on the part of Telmex that prevented the realization of these important regulatory actions.

B. Identification of the problem

As a consequence of consolidation carried out in Mexico in the period of 1999-2002, at the present moment, the year 2013, México accounts for 397 ASL, which:

- 199 ASL (in white color. See scheme 1) have only a single long-distance service provider and in the segment for local telephony services these ASL account for numerous providers. It should be noted that by saying there is a single long distance service provider implies that this specific service areas doesn't account for interconnection points. This was because of the government policy[40] to maintain artificially exclusion to long distance competitors so as to allow Telmex investment recovery in rural areas with income generated from m the traffic on these 199 ASL

- 198 ASL (in dark color. See Scheme 1) with numerous long distance service providers, implying hence the existence of interconnection points and local competition.

The calls that are made within a ASL are considered as local calls, while calls that are made between different ASL, are considered long distance calls.

Figure1. Geographical distribution 397 ASL in Mexico

Source: SCT, 2009

That is, only in 49.8% of the total ASL in national territory there are conditions for operators to interconnect with incumbent networks.

The current market distribution of fixed telephony services in Mexico, from the point of view of economic theory is inefficient by not allowing the entry of competitors for the provision of services in the long distance segment in 199 ASL, and neither to ensure best prices and quality for these services to users, however Telmex has defended the

[40] In accordance with article 62 and 63 of the LFT, conditions 5-2 and 6-2 concession title and section IV of article 31 constitutional

argument that the current setting of ASL is necessary for the viability of rural telephony services[41].

In this sense, the current configuration of ASL, which is slightly less than fifteen years old, produces a market of fixed telephony services in Mexico with inequalities between operators and significant costs to service users, mainly because a proportion of national territory calls courses between different ASL, which means paying higher fees to the cost of a local call.

To the extent that the geographical coverage of the ASL with interconnection points is extended, it would be more likely that users have greater choice in the provision of services, since the lack of interconnection points in those ASL has resulted in barriers to entry for potential competitors, which must be resolved with the implementation of the draft in comment.

C. Objectives of the intervention

Given the current technical feasibility, it is possible the entry of new competitors in the 199 ASL in which only Telmex operates, so that the Mexico Government seeks to make efficient use of the country's telephone infrastructure, and improve service, with more alternatives and better rates.

D. Regulatory alternatives

The alternatives identified and evaluated to solve the problems described above, were:

- ***Baseline scenario (Not issuing any regulation)***

In this case the *status quo* prevails, inefficient interconnection scheme that does not allow the entry of competitors in the provision of telecommunications services in the 199 ASL in which the country is divided, and thus continues the high costs of long distance in calls of users located in neighboring towns. Cofetel estimated cost of maintaining the status quo at about 2,492 million pesos a year (see section cost-benefit analysis).

- ***Another type of regulation***

Cofetel considered the possibility to make a modification of the numbering for technical implementation of the consolidations, however this would involve renumbering about 15 million users, and it would be a high damage to users who are have had to change the number they would have to notify the new phone number to all their relatives, acquaintances, suppliers, customers, etc., with the inevitable risk of losing some contacts.

- ***A different configuration of consolidated ASL***

[41]The new Federal Telecommunications Institute (IFT) ─ autonomous body of the Federal Government which replaced the Cofetel, since the Constitutional Reforms on Telecommunications adopted on June 11, 2013 ─ is currently preparing the legal defense to the ASL Consolidation Resolution to stand a constitutional rights trial filed by Telmex, in a specialized court of antitrust, broadcasting and telecommunications matters, which according to the telecommunications reform in June 2013, the general rules, acts or omissions that Ifetel issues, may be opposed only through indirect constitutional trial and will not be subject to suspension. In this sense, Telmex said that it will diminish the incentive to expand network coverage and affect the financial viability of rural networks, which complicates the feasible to upgrade and to achieve technological developments in these networks.

Also the regulator considered the alternative of various configurations of the number of consolidated ASL. In this regard, indicated that the proposed 172 ASL responded to the demands of users, authorities and operators.

Thus, with the proposed regulation ASL consolidation intend to move out of a total of 397 existing ASL to 172, so as to better take advantage of interconnection points in the country and to give a more efficient national telephone infrastructure.

In this regard, it is worth to mark that the consolidation of the ASL , first, assumed increases in the productivity of the economy as a whole, derived from the users of these services will have the ability to carry traffic at lower rates than current and, secondly is possible that the regulatory proposal could have an effect on the supply of telecommunications services to encourage the presence of a greater number of operators for this service in different areas of the country, since enabled interconnection points in the consolidated ASL could reduce the costs of local operation and thereby encourage attendance from different providers in these service areas .

Also, as the consolidated ASL will have a greater number of users with whom people can establish calls at local rates, the service will become more attractive and affordable for new users, and will also encourage the entry of more competitors to the local service, which potentially will result in higher levels of penetration of local telephone services and will involve traffic reduction resale by operators who provide this service, thereby promoting an efficient use.

Therefore, the regulatory proposal is an update of various provisions to adapt to new communication needs of the country taking into account requests from users, authorities and operators. In this regard, Cofetel proposed several regulatory actions, mainly the following:

1. **Obligation of the Operators of spreading Consolidation Process Information to Users.** A requirement for local and long distance service operators to inform users about the population of their respective consolidation.

2. **Technical Implementation of the Consolidations.** It is modified the procedure of dialing local calls established in PTFN and it is set the national number as the Regional Identification Number (NIR) + local number.[42].

3. **Obligation to Provide at least one point of interconnection.** It is established that local service operators must make available at least one interconnection point in the consolidated ASL, through which will be accessible to all the operator's users.

4. **Consolidation Calendar.** The regulatory proposal established a calendar for consolidations in the country on a 24-month horizon.

[42]For further reference of the structure of the national number refer to 5.2.2 numeral of the PTFN in force.

E. Impact Assessment

Cofetel identified the direct economic costs generated by the rules in force, as well as the direct economic benefits of this regulatory project; so that made a comparison of the costs and benefits of the *status quo* versus the costs and benefits of the implementation the proposed draft.

The methodology used by Cofetel was to identify the direct economic costs generated by the regulation as well as the direct benefits associated with its implementation, considering the following assumptions:

- An evaluation horizon of 10 years.
- A discount rate of 12 % in accordance with the guidelines in the evaluation of social investment projects of the Ministry of Finance and Public Credit.
- An approximately 9 % traffic contraction of long distance services.
- A zero cost for the installation of interconnection links.
- A cost of local and long links distance equal to the monthly rent (including discounts) established in the interconnection agreements for a single tract without additional charges per kilometer.
- A value of Price Elasticity of Demand for local service of -0.423.
- A 2.46% price service reduction
- The entrance of five operators in the 199 ASL to compete with Telmex in long distance services.
- An estimated market value of local telephone of approximately $560,012 million for 2012.

a. Direct costs of the project

Cofetel identified as direct costs of the project, the following:

1) Decrease in long distance revenues of Telmex, and
2) Investments for changes to billing systems and 10-digit dialing for local calls.

Table 1. Cost Analysis

Costs	Unitary ($ pesos)	Total NPV[43] ($ pesos)
1) Costs for decreased incumbent operator revenues	1,900,000,000	10,735,423,753.98
2) Costs of investment required to migrate to 10-digit dialing	136,220,000	121,625,000.00
Total Costs	*2,036,220,000*	*10,857,048,754*

Source: COFETEL- MIR annex "28786.177.59.1.costo-beneficio ASL.pdf"

b. Costs for declined incumbent revenues

The decrease in long distance revenues for Telmex would amount to savings for long distance users, since they would stop paying an extra on those rates. Cofetel estimated that the consolidation proposal consisting of reducing from 397 to 172 ASL involve a 9%

[43] Net Present Value.

contraction of long distance national traffic. That is, the 9% of long distance minutes that are made nationwide will be considered local calls, once all consolidations are made.

As national income for long distance service totaled $ 21,112 million pesos during 2012, considering a 9% of total revenues, this will mean savings for users $ 1,900 million pesos a year.[44]

c. Investment Costs of Migrating to 10-Digit Dialing

The technical implementation of the ASL consolidations proposed by Cofetel can be done by modifications in the billing systems, which require a minimum investment by operators. However, with regard to 10-digit dialing for local calls Cofetel said that this dial scenario was contemplated from the issuance of the Basic Technical Numbering Plan of 1996, so a 10-digit dialing is not derived from the implementation of this draft.

Moreover, Cofetel said that if local mobile and fixed service operators had to incur in costs for changing their billing systems to allow 10-digit dialing for local calls, a cost-based evaluation exercise was conducted that led to the implementation of number portability in 2008. [45]

Even though Cofetel considered that the implementation of number portability required changes much more significant in networks, states that the operators of local mobile service had to invest 4 million USD in their systems, while local fixed service invested 7 million USD. In total, for the concept of systems, the investment was 11 million USD, equivalent to 136,220 million pesos, at an exchange rate of $ 12.3841 pesos (12.3841 x 11,000,000).

d. Direct benefits related to the project:

Cofetel identified as direct benefits of the regulatory proposal:

(1) Long Distance Savings from Users,
(2) Savings in Interconnection links and,
(3) Increased demand for local traffic.

Table 2. Benefit Analysis

Benefits	Unitary ($ pesos)	Total NPV ($ pesos)
1) Long Distance Savings	1,900,000,000	10,735,423,753.98
2) Interconnection Links Savings	10,113,600	285,720,478.10
3) Higher Local Traffic Demand	582,520,000	3,291,367,918.51
Total Benefit	*2,492,633,600*	*14,312,512,150.6*

Source: COFETEL- MIR annex “28786.177.59.1.costo-beneficio ASL.pdf”

e. Long Distance Savings to Users

[44] This data is obtained by multiplying the 9% contraction to total revenue traffic in Telmex domestic long distance services, i.e. 0.9 x 21,112 million.
[45] *The benefit-cost analysis of number portability in México can be seen in the following link:* http://www.cft.gob.mx/work/models/Cofetel_2008/Resource/13053/DRMCONSULTING_Analisis_costo_beneficio_de_PN_en_Mexico_Publico1.pdf

Cofetel estimated that reducing ASL from 397 to 172 would involve a 9% contraction of long distance traffic nationally. That is, the 9% of long distance minutes that are made nationwide will be considered local calls once all consolidations are made.

While national income by long distance service during 2012 totaled 21,112 million pesos, considering a 9% of total revenues, this will mean savings for users 1,900.08 million pesos a year.

f. Interconnection Links Savings

Cofetel noted significant savings for telecommunications services providers associated with the links required to interconnect their public telecommunications networks. In this sense Cofetel notes that in 199 ASL there is no interconnection point, so that if an established local telephone operator in one of these areas without interconnection would like to interconnect, would have to hire a long distance link to carry traffic to where the incumbent has an interconnection point. In this regard, in order to estimate the savings in interconnection links, Cofetel considered a representative local service operator with nationwide coverage.

If this representative operator wanted to interconnect at all ASL, would require at least the following interconnection links: 198 local interconnection links and 199 long distance interconnection links. Being this the minimum infrastructure necessary because, depending on the volume of traffic and/or to take redundant interconnection routes may require two or more links for interconnecting each ASL and even the need to interconnect with various long distance operators.

Based on information contained in the Tariff Book of Telmex, since September 2, 2005, the 2 MBPS (E1) digital links show the following rates:

Table 3. Fixed monthly rates

Coverage	Km Range	Installation Expense by Segment	Monthly Income by Segment	
			Fixed	Fee/ Km
Local	N.A.	$90,971	$5,521	N/A
National	0-81	$12,293	$9,916	$226
	81-161		$20,830	$168
	161-805		$39,153	$64
	805-más		$55,228	$46

Source: Tariff Book 004925, TELMEX S.A. de C.V., 2005

Also, to estimate the costs of local and long distance links, Cofetel reviewed several interconnection agreements between existing public telecommunication networks. For this, Cofetel established the following assumptions:

Table 4. Cofetel Assumptions

Assumptions/Justification	
i. Installation costs are ignored	As this costs impact only once, and in case the networks are already interconnected, these are savings that will no longer be in the future.
ii. Local links costs	For local links, it would only be considered the cost of a stretch. ($ 4,375.00 - 57% discount = $1,881.25 pesos monthly rental).
iii. Long-distance links costs	For long-distance links it is only considered a link, without considering an additional local tract and without additional charges per kilometer, since consulted agreements do not specify whether in the long distance link charge an additional local track is applicable, the result of the savings that will estimated will be the most conservative. ($ 4,375.00 - 57% discount = $1,881.25 pesos monthly rental).
198 ASL with local link (cost)	*198x$1,881.25 = $372,487.5*
199 ASL with long-distance link (cost)	*199x$1,881.25=$374,368.75*

Source: COFETEL- MIR annex "28786.177.59.1.costo-beneficio ASL.pdf"

So to estimate the savings due to lower interconnection links it is required 1) to calculate links costs in a configuration of 397 ASL and 2) subtract to this amount the cost of the links with a configuration of 172 ASL, and also considering that costs only relate to *origination traffic*, so it must be multiplied by two to also consider *termination traffic*.

The first point was estimated considering a monthly rent for local and long distance link for $1,881.25 each, so the monthly cost of the links is equal to 397 x 1,881.25 = 746,856.25 which doubled to consider both directions of traffic (origination and termination) results in a total monthly cost of 1,493,712.5 pesos, which implies an annual cost of links in the 397 ASL of 17,924,550 pesos.

For the second point, to have 172 ASL, the cost drops to 650,912.5 pesos a month, which represents an annualized amount of 7,810,950 million pesos.

Therefore, **total savings derived of the interconnections links results in 10,113,600 pesos ($17,924,550- $ 7,810,950).**

g. Increase in the demand for local traffic

Cofetel considers that consolidation could have a possible network effect, i.e. an increase of local traffic as a result of a greater number of destinations that you can call local rate.

However, the Cofetel is limited to scan only the increase in traffic that will occur as a result of the reduction in the cost of phone calls going from long distance to local rate, i.e. the direct benefit of the increase in demand for local traffic.

In this regard, it is noted that when performing the proposed consolidations, and consider that at least 9% of the total long distance traffic is now considered local, the benefit may be approximated as a decrease in the cost to users.

Cofetel also noted that a long distance call rate is comprised of the following elements:

Tariff of Long National Distance that the user pays	=	*Local Call (measured service)* *or* *Local air time on mobile*	+	*Per minute rate for concept of national long distance*

On this matter, the Cofetel to calculate the decrease of prices that will observe the national market of local telephony and of long distance, considers the income that were obtained for these services during the year 2012, limiting itself to the market of fixed telephony.The Cofetel conducted an exercise of price elasticity of demand in order to estimate the percentage increase in the quantity demanded derived from a percentage reduction in the price.

For it, the percentage reduction of the price comes closer with 2.46 % derived from the least revenue by concept of the services of long national distance. The decrease in the cost that this measurement implies, will turn out to be reflected in a major demand by the service, in accordance with the equation of elasticity price of demand that is described next:

$$\text{Equation of elasticity price of demand } = \mathrm{n} = \frac{\Delta\%\mathrm{Q}}{\Delta\%\mathrm{P}}$$

Where:

$\Delta\%$Q is the percentage change in demand
$\Delta\%$Pis the percentage change in price.

The interpretation of the price elasticity of demand (n) is given by the following table:

Value of n	Clasification	Interpretation
-1 < n < 0	Inelastic	Percentage change in demand is less than the percentage change in price.
n = -1	Unitary elasticity	Percentage change in demand is equal to the percentage change in price.
-∞< n < -1	Elastic	Percentage change in demand is greater than the percentage change in the price.

Then cited, as an example, the result of a study about elasticities in Colombia for different types of telephone service is:

Mobile service: For post-payment they calculated-1.38, while for prepayment they point out that it is between-0.87 and-1.06.

Local service: Local phone (local-local), give service price - 0.423 and - 0.927, indicating that before the price increases consumption decreases.

Long Distance Service: price elasticity between -0.956 and -0,970 , this is very close to -1, which means that there is an inverse relationship between the demand for the service and the prices of the same.

In order to calculate the most conservative stage as for traffic increase for the decrease that the users will perceive in the prices, there will be realized the calculation with the value of Elasticity Price of the Demand of-0.423 for the local service.

Price elasticity of demand	*Increase in the demand of the local service*
-0.423	*ΔQ = (-0.423)*(-2.46%) = 1.04 %.*

However, taking into account the estimate of Cofetel of the national market for local telephony around $560,012 million pesos for the year 2012, the implementation of the consolidation of the ASL will involve a percentage increase in the quantity demanded of calls of 1.04 %, which represents a total increase in the total market value of $582,520 million pesos a year, i.e. [1.04 x 560.012].

h. Non-quantifiable benefits

Additionally, this Dependence indicated not quantifiable benefits that stem from the draft in comment, which (who) are transcribed next:

- Greater competition in the quality and price of telecommunications services
- Will increase competitiveness for micro, small and large companies
- Greater regional integration, derived from the communication of small rural towns with cities or municipalities
- Reduction in costs of transaction of nearby localities, on having avoided the transfers of one locality to other one because they can communicate between localities by means of local calls instead of long distance calls.
- The barriers to communication will be reduced for small towns and metropolitan areas users.
- By dialing 10 digits in calls to local numbers, users will be able to use the function "call-back" in your terminal equipment without having to edit the number they receive on their caller ID. This will result in a higher rate for local calls completed.

i. Analysis on net present value of the ACB of the preliminary draft

The Cofetel considered a horizon of evaluation of the regulation of 10 years with a social valuation rate of discount of 12 %.

Table 5.Cost-benefit analysis of the consolidation of the ASL in Mexico

Concept	Unitary ($ pesos)	Total VPM ($ pesos)
Costs		
Dealer incumbent revenues decreased costs	1,900,000,000	10,735,423,753.98
Investment costs required to migrate to 10-digit dialing	136,220,000	121,625,000.00
Subtotal costs	*2,036,220,000*	*10,857,048,754*
Benefits		
Long distance savings	1,900,000,000	10,735,423,753.98
Savings in interconnection links	10,113,600	285,720,478.10
Increased demand for Local Traffic	582,520,000	3,291,367,918.51
Subtotal benefits	*2,492,633,600*	*14,312,512,151*
Net Benefit	**456,413,600**	**3,455,463,397**

Source: COFETEL- MIR annex "28786.177.59.1.cost-benefit ASL.pdf"

Therefore the implementation of the preliminary draft would have net annual benefits of about $456 million pesos, which represented to a horizon of evaluation of 10 years the amount of $3,455 million pesos. The estimate of the Social Net Present Value, is an indicator that showed in monetary terms that the preliminary draft would provide greater benefits than costs to society.

F. Choosing the best regulatory alternative

The regulatory proposal was regarded as the better alternative because it represents positive social benefits; since maintaining the status quo, there would be no savings for users of telecommunications services arising from the reduction of the expenditure by the payment of calls that before were long distance and that, with the consolidation of the ASL, they become local calls.

The same way, the regulative project was considered to be the best alternative, since he(she) considered the consolidation of regions that keep a narrow economic and social link, for the purpose of allowing the communications between its inhabitants to be a cost efficient, that is to say, that the tariff that the users of these services pay does not reflect distortions derived from the territorial arranging that will be able to be provoking barriers of economic entry for the social groups located in the adjacent areas that do not belong to the same ASL[46].

In addition, based on opinions and studies of international agencies such as: the reference document for the World Trade Organization and the International Telecommunication Union and the recommendations of the Strategic Agenda for the reforms in Mexico 2013, disseminated by the Organization for Economic Cooperation and Development (OECD), **the consolidation of the ASL is a regulation in line with international best practices.**

[46]Derivative of the public consultation realized during the process of regulatory improvement, the following requests were received: Apizaco with Tlaxcala on the part of the Secretariat of Communications and Transports of the Government of the State of Tlaxcala, Cozumel with Cancún and Altamira with Tampico on the part of diverse concessionaires of public networks of telecommunications.

G. Final remarks

It is considered that there are various regulatory actions that may be provided an additional justification, with the aim of showing the effects that pursues its implementation and to ensure that these permit the best implementation of the proposed regulation

i. Methodological Challenges

A methodological challenge would have been to shape the strategic behavior of users under changing telephone rates. In addition, it would have been calculating the behavior of traders seeking to maximize their profits. This setting could have lead to fewer benefits tan that said bye the regulator in the comments box of cost benefits of its preliminary draft.

ii. Challenges of estimation

The challenge of estimating this proposal in particular consist of justifying, in a reasonable manner, the various assumptions set out in the analysis, but in a more rigorously frame.

In this particular case, Cofetel meant that a contraction of 9% would be in the traffic of long distance calls. So it would have been advisable to estimate this percentage based on econometric techniques or by some sort of estimation such as for example, an international benchmarking of cases similar to the one in Mexico.

Another assumption was that related to the necessary amount of investment that should be done in the operators to implement the model to the dial of 10 digits. In this case the regulator opted instead to bring the approximate cost used in the model of number portability in 2008. However it is questionable whether in this case there would be the same number of users who benefited from the number portability as those that would benefit from the consolidation of the ASL. For the foregoing reasons, in the event that they are different, it would have been necessary to make the relevant adjustments. In addition, it is questionable whether it's the same amount of investment in both models.

iii. Challenge of reducing bias

Another major challenge was to consider the possible bias that may have experienced the regulator when identifying the costs and benefits in the preliminary draft. For example, if the governor was in favor of a certain type of regulation he could have exaggerated the benefits versus the costs. That is why it reiterates the importance of a thorough analysis. So it is possible to identify two areas for improvement: a methodological and another one in the implementation.

H. References

Agenda Estratégica para las Reformas de México de 2013 de la Unión Internacional de Telecomunicaciones (UIT), y el Documento de Referencia de la Organización Mundial de Comercio (OMC) 2013, ambos difundidos por la Organización de Cooperación y Desarrollo Económicos (OCDE)

COFEMER, Regulatory Impact Assessment (RIA) of the regulatory proposal: http://207.248.177.30/regulaciones/scd_expediente_3.asp?ID=10/0649/090413

COFETEL- MIR anexo “28786.177.59.1.costo-beneficio ASL.pdf”

García, Y., "Estado del Arte: Elasticidad Precio, Ingreso y Cruzada de los servicios de Telecomunicaciones en Colombia". consultado el 21 de marzo de 2013. Disponible en: http://www.interactic.org.co/index.php?option=com_docman&task=doc_details&gid=52&Itemid=

OCDE, Reforma Regulatoria en México, Volumen 1, 1999

Odlyzko, A. & Tilly, B. (2005) de la Universidad de Minnesota "A refutation of Metcalfe's Law and a better estimate for the value of networks and network interconnections: n*log(n), 2005

TELMEX S.A. de C.V., (2005), Libro de Tarifas 004925.

I. Problems the regulator faced when evaluating the regulatory impact.

The difficulties presented by the regulator in order to be able to measure the impact of the regulation were the following:

- The benefits of savings of interconnection links. The difficulty faced by the regulatory body was that there are a variety of conventions of interconnection, tariff information local telephony and fixed dates back to the Book of rates of Telmex in 2005. In this regard, the regulatory body faced this situation pose several assumptions in order to make an estimate, such as skip installation costs, consider only the cost of a sections of the local links, and in the case of long distance links only will be considered as a link, without considering an additional local stretch and without additional charges per kilometer, any time that the conventions consulted do not specify if the link long distance will be charged an additional local stretch, in your case, the result of the savings that is expected to be the most conservative.

- The benefits by increase in demand for local traffic. In this case the difficulty faced by the regulatory body was the possible effects of network on the estimate, i.e. an increase of local traffic as a result of a greater number of destinations that you can call local rate. In this regard, Cofetel is limited to scan only the increase in traffic that will occur as a result of the reduction in the cost of phone calls going from long distance to local rate, i.e. the direct benefit of the increase in demand for local traffic.

Matter or regulation:	**Reclassifying the Medical Device of Low Risk**

Type of regulation *(Choose the preponderant one)*	( ) Economic regulation ( ) Administrative Regulation ( ) Two, indistinctly. Specify:	(**X**) Social Regulation ( ) All without difference

Implemented methos *(You can choose more than one)*	(**X**) CBA ( ) Multicriteria Analysis ( ) Annual Equivalent Cost	( )CEA ( ) Another, specify.

Apply methodologies *(You can choose more than one)*	( ) Contingent valuation ( ) Transportation cost ( ) Disease cost ( ) LSV ( ) AVAD ( ) Transference of benefits ( ) concentration coefficient ( ) Dominancy Index ( ) General equilibrium analysis (**X**) Standard Cost Model	( ) Hedonic Prices ( ) Defense expenses ( ) Capital human method ( ) QALY ( ) Compensatory variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index (x) Another, specify

Decision criteria	( ) Sensibility Analysis ( ) Rate of Return (**X**) Another, specify: **Benefits greater than costs**	( ) Monte Carlo method ( ) Internal rate of return

Case 11. Agreement that shows the list of inputs for the health that are considered as low risk for obtaining the COFEPRIS[47] register effects, and those products that for its constitution, own characteristics and uses are not considered as inputs for health and therefore do not require COFEPRIS register.

A. Introduction

Concerning to the rules of inputs for the health (RIS for the Spanish Reglamento de Insumos para la Salud) in Mexico, we can consider that a medical device is a substance, mix of substances, material, system or instrument (including the computer program necessary for its appropriate use or application), only or in combination using in the diagnostic, supervision or prevention of diseases in humans or auxiliary in the treatment of the diseases and disability, also the ones used as replacement, correction, restoration or modification of the anatomy or human physiological process.

In the 2011, the medical devices were classified in three categories, where the Class I include the devices of lower risk and the Class III those of higher risk, according to the next:

> **CLASS I.** Those inputs that generally are well known in medical practice and its security and efficacy are confirmed and, generally, are not introduced into the body.
>
> **CLASS II.** Those inputs that generally are well known in medical practice and that may have variations in the material which they are made of or in its concentration and, generally, are introduced into the body while remaining less than thirty days.
>
> **CLASS III.** Those new inputs or recently accepted in the medical practice, or that are introduced to the body for more than thirty days.

For article 86 of the RIS, it is shown that, independently of the classification of the devices, all of them require a COFEPRIS **sanitary registry**, which means that they most have an authorization[48] by the sanitary authority, for manufacture, importation, storage, distribution and commercialization in Mexico.

Such authorization must be filed at the COFEPRIS, whom has a presenting list of requires, and it has to be waited for the State resolution, depending on the type of device: 30 days for those of the class I, 35 business days for those of the class II and 60 business days for those devices of the class III. The General Health Law states that the mentioned register could be extended every five years. At the same time, the same Law indicates that for the cases where the applicant does not apply for the extending time after the period stipulated for it or after changing or modifying the product or the maker raw material, without a previous authorization of the sanitary authority; then such authority will proceed to suspend the place.

[47] COFEPRIS (for its initials in Spanish) is the Federal Commission for Protection against Sanitary Risks, or Comisión Federal de Protección contra Riesgos Sanitarios

[48] The article 368 define the sanitary authorization as the administrative act by which a competent sanitary authority allows to a public or prívate person, the realization of activities realted to the human health, in the cases and with the requieres and modalities that determines this Law.

In the same way, if the medical devices were made in the abroad, at the moment of its importation, must be presented, at the sanitary authority, a **previous permission of importation,** which can be solved to within 40 business days.

For this sense, until 2011 the importers or manufacturers of medical devices in Mexico had to meet the following: [49] [50] **[51]**

COFEPRIS registration	Extension of the registration	Previous importation permission
Response period of the authority 30 business days	Response period of the authority: 150 days	Response period of the authority: 40 business days
1. Properly completed form. 2. Technical and scientific information to demonstrate that the input has the security and efficacy characteristics. 3. The project has the label in agreement to the corresponding Mexican rules. 4. If it is necessary, the instructions for the use or the operation manual in Spanish. 5. Overview of the process of manufacturing the product. 6. Description of the structure, materials, parts and functions of the product. 7. If it is necessary, the constancy of good manufacturing practices. 8. Lab tests to verify input specifications. 9. References (bibliography). 10. Industry agreement. 11. The requested in the Mexican rules (NOM for its initials in Spanish – Mexican Official Norms). 12. Proof of payment of fees.	1. Properly completed form. 2. Proof of payment of fees. 3. Number or copy of the COFEPRIS registration which the extension is requested and its amendments. 4. The previously authorized labels, instructions or manuals. 5. The technical-vigilance inform for each product, in agreement with the rules in the topic. 6. Analysis certificate issued by the company, with the letterhead of the official name of the company signed by the COFEPRIS person in charge or similar. 7. The certificate of good manufacturing practices. 8. Original COFEPRIS authorization and, if is require, the authorization of the modifications. If the original COFEPRIS authorization is not available, then must be filed the original document of the prosecution before the Public Ministry (Ministry Bureau) about loss or theft.	1. Copy of COFEPRIS license or notice of the corresponding operation. 2. Copy of COFEPRIS registration and its modifications, including the copy of the authorized labels.

B. Identification of the problem

Because the medical device definition is very broad, almost any instrument that was related to the healthcare medical device was considered. **However, the Mexican state indicates that there are 1,669 identified devices that by their nature, characteristics and use, do not imply risks to human health** as in the case of: mixers, pillows, masks,

[49] Process code: COFEPRIS-04-001.
Process name: Application for licensing medical devices
Available in http://207.248.177.30/tramites/FichaTramite.aspx?val=28845

[50] Process code: COFEPRIS-01-014
Process name: Sanitary import permit for medical device with health registration without containing narcotic or psychotropic.
Available in: http://207.248.177.30/tramites/FichaTramite.aspx?val=29903

[51] Process code: COFEPRIS-04-021-A
Process name: Request for extension of sanitary registration of medical devices
Available in: http://207.248.177.30/tramites/FichaTramite.aspx?val=24072

bibs, slings, gauges, beds, toothbrushes , wastebaskets, among many others; as well as other inputs that represent a risk close to zero, as is the case of the gauze, tape, or adhesive strips medical adhesives ("Band-Aids"), collars, cotton, robes, towels, microscopes, and so on.

From this perspective, we can observe that the regulation (2011) establishes entry barriers to new participants through expensive processes of sales and distribution by establishing unnecessary administrative burdens; in this sense it was identified that 1669 marketing medical device form a total of 12,000 do not represent risk to the health of the population.

C. Objective of the intervention

To eliminate or reduce the administrative burden on the issue of COFEPRIS registrations in order to promote competition, reduce entry barriers to medical device market through risk-based regulation.

D. Regulatory Alternatives

- ***Baseline scenario (Not issuing any regulation).***

If any regulation is emitted, then the status quo will prevail and the regulation will work for an inexistent risk and therefore the regulator will be over regulating (type II error) 1,669 devices that do not represent risk for the health. This situation cause administrative charges and unnecessary cost for the industry.

- ***Agreement of Deregulate and Reclassifying Medical Devices***

Through a regulatory proposal seeks to deregulate 1,669 medical devices that the regulator identified that do not represent health risk. Also, the regulatory proposal seeks to create a new category or class of devices, which will call **Class IA**, for medical devices at very low risk, which could get the COFEPRIS registration through a simplified procedure, i.e. the regulator intend to require fewer requirements. The Mexican state seeks to reclassify 96 Class I medical devices to IA.

Examples of devices

Medical devices declassified – deregulation	Medical devices reclassified to class IA- Administrative simplification
1,669 devices	**96 devices**
1. Counter needles. 2. Soaps of households use. 3. Surgical table 4. Sheets to cover an individual, reusable. 5. Armchairs for recognition / eye treatment. 6. Storage on x-ray film. 7. Arm supports. 8. Anesthesia stool. 9. Test tube. 10. Washing dental units. 11. Magnifying glass for surgery. 12. Gypsum shoes.	1. Cotton roll. 2. Surgical gowns, disposable and reusable. 3. Orthodontic wax. 4. Tapes, strips or adhesive for medical use. 5. Cervical collar. 6. Face mask. 7. Splints. 8. Muslin 9. Surgical towel. 10. Elastic bandage.

For this case, the 1,669 devices listed above, will not need the COFEPRIS registration process and thus their extension. While the 96 devices that are Class I changes to Class IA, the COFEPRIS registration process for these will be

simplified, including their extension. (See table below).

COFEPRIS registration	Extension of the registration	Previous importation permission
Response period of the authority 30 business days	Response period of the authority: 150 days	Response period of the authority: 40 business days
1. Properly completed format. 2. Proof of payment of fees. 3. The project of label in Spanish. 4. Copy of the authorization of the establishment. When adding foreign manufacturing; 1. Manufacturer representation letter.	1. Properly completed format. 2. Proof of payment of fees. 3. The project of label in Spanish. 4. Copy of the authorization of the establishment.	1. Copy of COFEPRIS license or notice of the corresponding operation. 2. Copy of COFEPRIS registration and its modifications, including the copy of the authorized labels.

E. Impact evaluation

Under the above considerations, we can determine that the study of authority has focused on the analysis of three regulatory alternatives, the impact of which is described below:

- ***Baseline scenario (nor issuing any regulation)***

This regulatory alternative preserves the *status quo* of the authorization scheme of medical devices. In this sense, it can be noted that, in the event that the authority had chosen this alternative it wouldn't have been possible to generate benefits for the industry, and thus to consumers. ***So then, we can assume that the cost of maintaining the status quo would be equivalent to the benefit of making the proposal*.**

- ***Agreement of deregulate and reclassifying medical devices***

Since the impact of the regulatory proposal is to reduce administrative burdens the Mexican State was given the task of measuring the administrative burden of the paperwork through the Standard Cost Model (SCM)

For this regulatory alternative, it was identified the resource saving benefits for decreasing the administrative burdens, which are:

- **Resource saving benefit payment rights in health records for 1,669 medical devices**

If there are 1,669 covered products that are no longer require for sanitary registration manufacture, import, packaging, storage, distribution or marketing, and we consider that each product had minimally 3 retailers or marketers that should have health registration, it is expected that at least 5,007 are left out of the process medical records.

Number of Registration	Cost of the Registration	***Total Year Savings***
5,007	7,967	*$39,890,769.00*

- **Extensions**

The medical records were valid for five years so it is estimated that each year were renewed the 20% of all records, (i.e. 1,001) so it is expected an annual savings of $7,974,967.00 pesos.

Number of Registration	Cost of the Registration	*Savings per Year*
1,001	7,967	*$7,974,967.00*

- **Benefit for the resource saving of the import sanitary payment rights for 1,669 device types permits**

In the case of devices to deregulate doesn't require a prior import permit for the entry to the country, each request has a cost of 1,505 pesos. According to information provided by the Commission of Health Authorization of the COFEPRIS, in the 2010 there were 9,397 import sanitary permits Class I Medical Devices. Assuming that at least 50% of the records correspond to devices that are unregulated and do not require sanitary import permit, then there must be about 4,699 sanitary permits, that imply an amount of 7,071,995 pesos of savings of the import sanitary permits.

Number of Import Sanitary Permits	Permit Cost	*Total Savings*
4,699	1,505	*7,071,995*

- **Benefit to save resources by eliminating administrative burdens for health registration for 1,669 device types**

With the SCM it was measure the administrative burden and the opportunity cost of performing the procedures of the sanitary registry for licensing, extending and import permit, obtaining the following:

Economic cost of the procedure of approval:

Using the information provided by industry, it was determined that a representative firm can allocate approximately 79 days in the preparation of the information required to apply for registration of a health medical device, of which approximately 60% corresponds to the time of managers, 10% of professional staff, and 30% to the secretarial staff or assistance. Therefore, considering the data and documents that individuals should perform, and with activities inside and outside the company as well as the time it takes for the authority to resolve and considering the Weighted Average Cost of Capital of 14.35%, we get the following:

a. Economic Cost of Procedures

Process	Administrative Burden per Process	Opportunity Cost per Process	Economic Cost per Process	Frequency
Sanitary Registration	$13,974.46	$2,172,283.62	$2,186,258.08	5,007
Prorogation	$12,983.30	$8,689,134.48	$8,702,117.78	1,001
Previous License/Permission	$2,242.75	$3,243,944.53	$3,243,944.53	4,699

By considering the frequency for each process, we get the aggregate costs as shown next:

Process	Aggregate Administrative Burden	Aggregate Opportunity Cost	Aggregate Economic Cost
Sanitary Registration	$69,970,121.22	$10,876,624,085.34	$10,946,594,206.56
Prorogation	$12,996,283.30	$8,697,823,614.48	$8,710,819,897.78
Previous License/Permission	$10,538,682.25	$15,243,295,346.47	$15,243,295,346.47
Total			*$34,900,709,450.81*

- **Resource savings benefits by the administrative simplification of 96 types of medical devices**

Derived from the regulatory project, it was observed that sanitary registration applications and its corresponding prorogation of 96 types of medical devices reclassified as Class IA, would be less expensive, when requirements were reduced from 11 to 4. Likewise, based on the SCM methodology, it was anticipated that the **sanitary registration process** simplification of 96 devices would generate administrative burden release by application of $13,679.05 pesos[52]; while reducing the requirements that must be deliver to authority in corresponding **prorogation applications** would generate an economic liberation per application of approximately $5,996.64 pesos.

Process	Administrative burden per Initial Process	Administrative Burden per Simplified Process	Resource Savings in Administrative Burden per Process	Frequency
Sanitary Registration	$13,974.46	$295.41	$13,679.05	96
Prorogation	$12,983.30	$6,986.66	$5,996.64	96

Thus, assuming regulatory project would generate authorization for at least one medical device for each simplified type, it was estimated that industry **economic resource liberation could be of $1,888,866.24 annual pesos**.

Process	Resources Saved for Administrative Burden Process	Frequency	Total Savings
Sanitary registry	$13,679.05	96	$1,313,188.80
Extension	$5,996.64	96	$575,677.44
Total			*$1,888,866.24*

- **Government resources benefit savings for the public inquiries not needed to respond.**

The COFEPRIS has pointed that attending public inquiries about medical equipment of low risk, generates costs. To this respect, the cost outlay represents about ***5 million MXP per***

[52] Present calculation consider pondered average in estimated savings for process *COFEPRIS-04-001* A, B and C modalities, according to the frequency they are presented.

year, which could be better used in other activities, after the release of the proposed regulation.

From the foregoing, the expected benefits are:

Benefit for deregulate 1669 medical devices	
Benefit for the resource saving in health records payment rights'	$39,890,769.00
Benefit for the Resource saving in royalty payments Deferment health records.	$7,974,967.00
Benefit for the resource saving in royalty payments for sanitary import permits.	7,071,995
Benefit for the save resources by eliminating administrative burdens of health registration.	$34,900,709,450.81
Subtotal	$34,955,647,181.81
Administrative simplification benefits of 96 devices	$1,888,866.24
Savings of government resources from the public inquiries that will not be necessary to reply.	$5,000,000.00
Total expected benefits	*$34,962,536,048.05*

F. Choosing the best alternative

According to the above, it was found that the best alternative was the release of the present Agreement from which its implementation would generate minimal costs to the industry and annual benefits of about **34,962.5.** In this case, because the **benefits were significantly much higher than the compliance costs**, it wasn't necessary to apply a decision-making criterion.

It also became clear that among the three proposed regulatory alternatives (not issuing any regulation, employing a self-regulatory scheme and the reclassification of medical devices), the stated Agreement was the best possible alternative, since without the emission of the regulation, it could be jeopardized the quality, safety and effectiveness of medical devices available to consumers in the market.

G. Final Remarks

The regulation was published in the Official Journal of the Federation on December 31, 2011. During the public consultation process, individuals expressed their support for the draft, considering the regulatory proposal in line with the industry characteristics. Its implementation was seen without negative consequences for the health of the Mexican population.

H. References

COFEMER, Regulatory Impact Assessment (RIA) of the regulatory proposal: http://207.248.177.30/regulaciones/scd_expediente_3.asp?ID=02/1036/111011

European Commission; *Measuring administrative costs and reducing administrative burdens in the EU.* November 2006. Can be consulted at the following link: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/425&format=HTML&aged=1&language=EN&guiLanguage=en.

OCDE, (2010). Risk and Regulatory Policy: Improving The Governance Of Risk. Can be consulted at the following link: http://www.oecd.org/gov/regulatory-policy/riskandregulatorypolicyimprovingthegovernanceofrisk.htm.

Matter of regulation	***"General guidelines for the sale or distribution of food and beverages at consumption establishments of basic education campuses"***

Type of regulation *(choose the preponderant one)*	( ) Economic regulation ( ) Administrative regulation ( ) Two indistinctly, specify:	(**X**) Social regulation ( ) All indistinctly

Implemented method (s) *(You can chose more than one)*	(**X**) CBA ( ) Multi-criteria analysis ( ) Equivalent annual cost	(X)CEA ( ) Other, specify:

Implemented methodologies *(You can chose more than one)*	( ) Contingent valuation ( ) Travel cost methodology ( ) Cost of illness method ( ) VSL (**X**) Disability adjusted life years ( ) Benefit transfer method ( ) Concentration índices ( ) Dominance index ( ) General equilibrium analysis ( ) Measurement of administrative burdens	( ) Hedonic prices ( ) Defense expenses ( ) Method of human capital ( ) Quality adjusted life years ( ) Compensating variation ( ) Consumer surplus ( ) Herfindahl index ( ) Lerner index ( ) Other, specify

Decision criteria	( ) Sensitivity analysis ( ) Immediate Rate of Return ( ) Other, specify:	( ) Monte Carlo method ( ) Internal Rate of Return

Case 12. General guidelines for the sale or distribution of food and beverages at consumption establishments of basic education campuses

A. Introduction

On June 10, 2010 the Ministry of Public Education (SEP, in Spanish) issued the draft regulation *"General guidelines for the sale or distribution of food and beverages at consumption establishments of basic education campuses".* This government measure is intended to reduce levels of obesity in children by restricting the supply of high-calorie products in schools, this, in order to prevent various diseases and conditions that often occur as a result of obesity and overweight.

B. Identification of the problem

Most people think that overweight and obesity are cosmetic problems that are not necessary to consider as matter of health. Nevertheless, obesity is one of the major causes of chronic diseases among population, such as type II diabetes, cardiovascular disease, osteoarthritis and breast cancer, among others, which notoriously decreases life expectancy.

The main consequence of obesity is the deterioration of health and life quality of the population. In this sense, governments should use significant amounts of resources to treat both the problem of overweight and obesity, as well as the temporary and permanent disabilities, the premature deaths and the diseases that derive from it.

Some relevant data on the problem of overweight and obesity is:

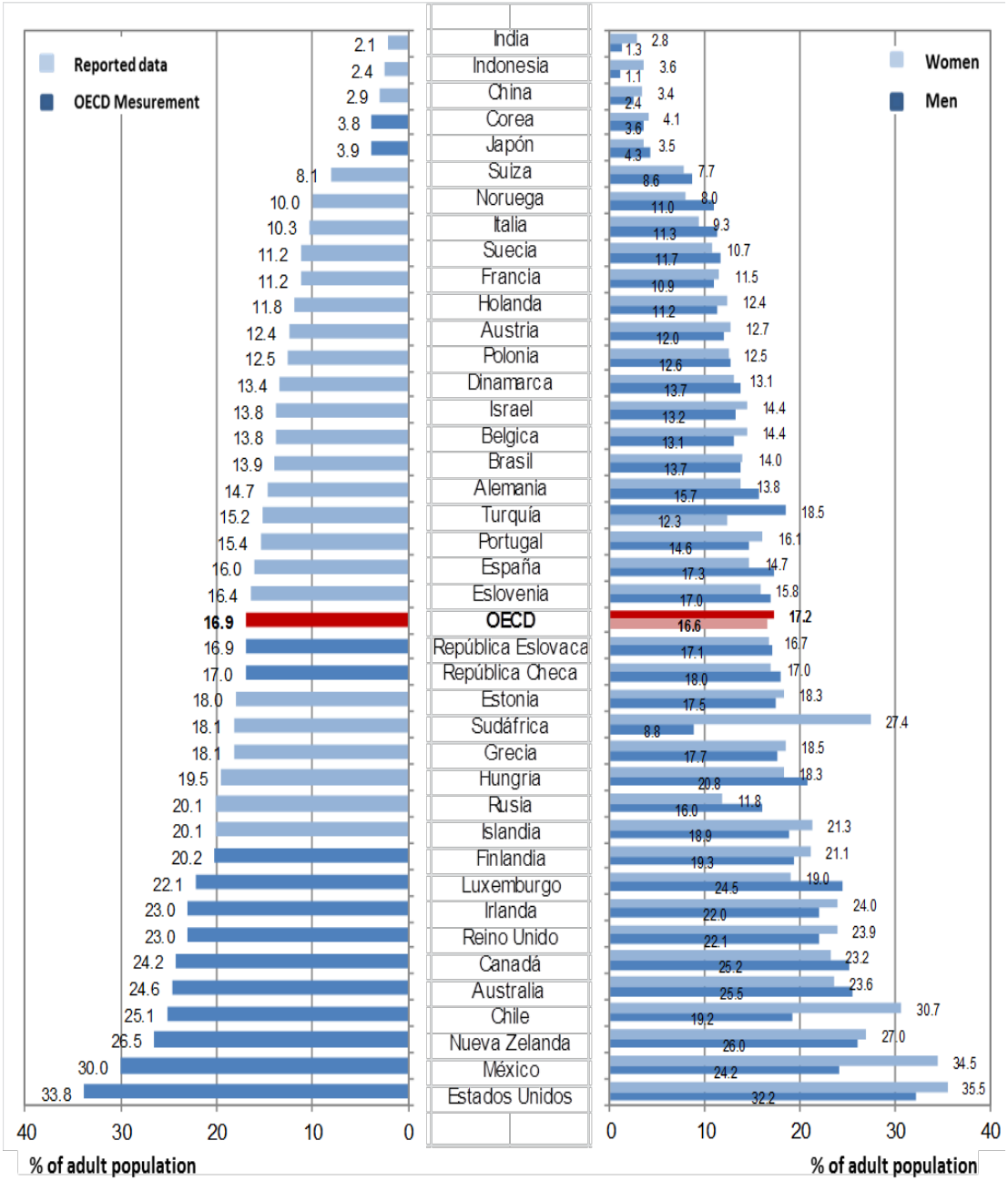
- 17% of the population in OECD countries is obese or overweight.
- Mexico is the second OECD country with the highest proportion of obese people in the total population.
- Seven out of ten adults are overweight or obese.
- Mexico ranks fourth with obese children (aged 5 to 17 years); one child in three is overweight or obese.
- In 2004, 75% of the deaths were mainly caused by diseases associated with obesity.
- It is estimated that in Mexico, during 2017, the costs of health from diseases associated with overweight will be around 150 billion Mexican pesos.

As noted, the widespread of obesity is a major worldwide problem. In Mexico, obesity and overweight are observed in all age groups and it experiences a rate of increase that has not been recorded in any other country. At the international level there is sufficient evidence to establish the contribution of this disease to the development of chronic diseases, which result in significant challenges for the national health system and for economic growth.

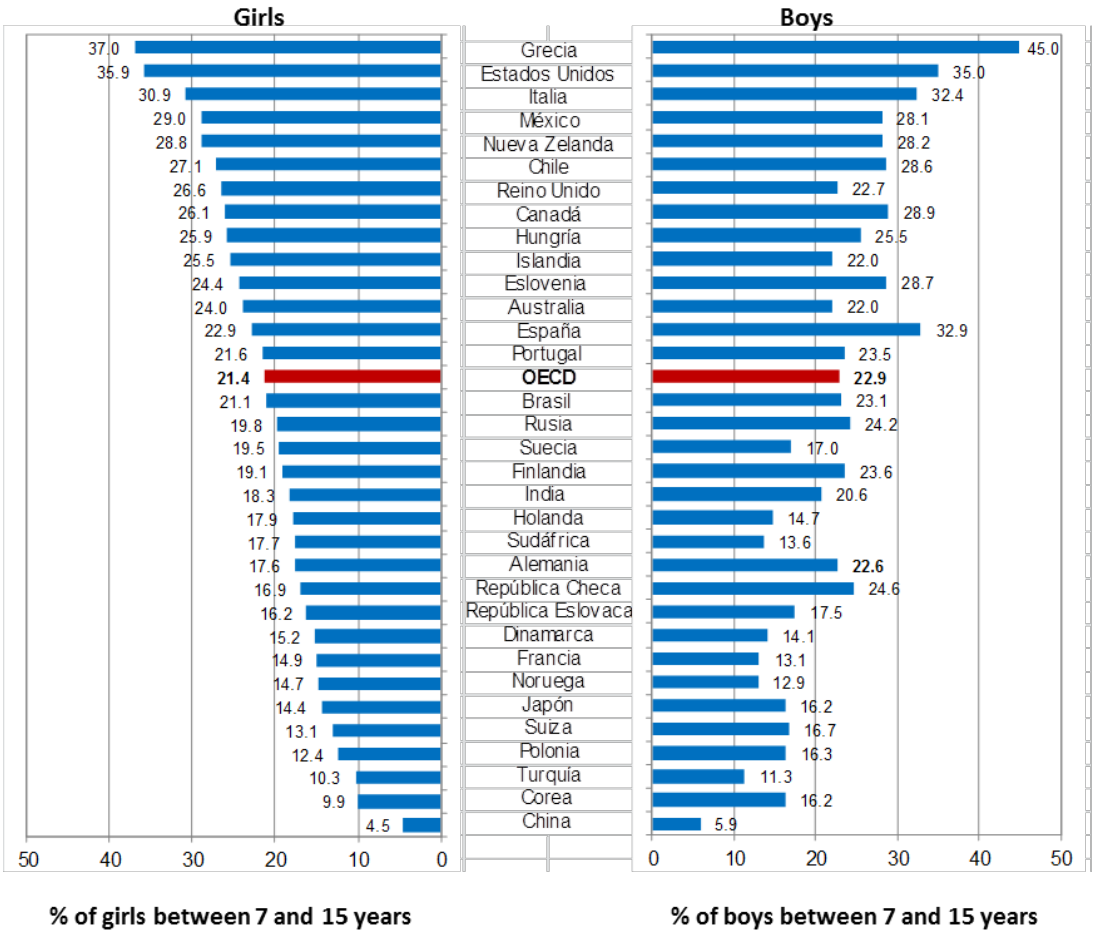
The incidence of obesity in Mexican population has increased significantly during last years. A significant proportion of this increase corresponds to children and adolescents aged 10-17 years, which boosts the probability of various diseases and conditions associated directly obesity in adulthood as well as the risk of death that can even threaten to reduce population life expectancy reached at the moment:

The charts below show the severity of the problem of obesity in Mexico compared to other countries:

Adult obesity rates, data from 2009 (or latest year available)



Rates of overweight (including obesity) for children and adolescents (5-17 years), latest year available



Source: OECD Obesity Update, February, 2012

So, in order to encourage the implementation and discussion of various preventive measures that have been established in Mexico, in 2010 the National Agreement for Health Food (ANSA) was issued. The last is an agreement between government and society aimed at the implementation of measures that lead to changes in social behavior, in order to reduce the prevalence of these obesity and overweight conditions.

As for the causes of the problem, the academic and scientific studies have shown that there are additional reasons that explain the occurrence of this problem, from which we conclude that obesity has a multifactorial origin and can be studied from various points of view, as may be the clinician, the nutritional, the social and the economic, among others.

The most widely accepted causes of this problem are:

- Balance: greater caloric intake than caloric consumption.
- Transition to diets with food of high contempt of fats, sweeteners and salts.
- Increase of fast and junk food consumption.
- Extensive exposure to advertising of low nutritional value food.

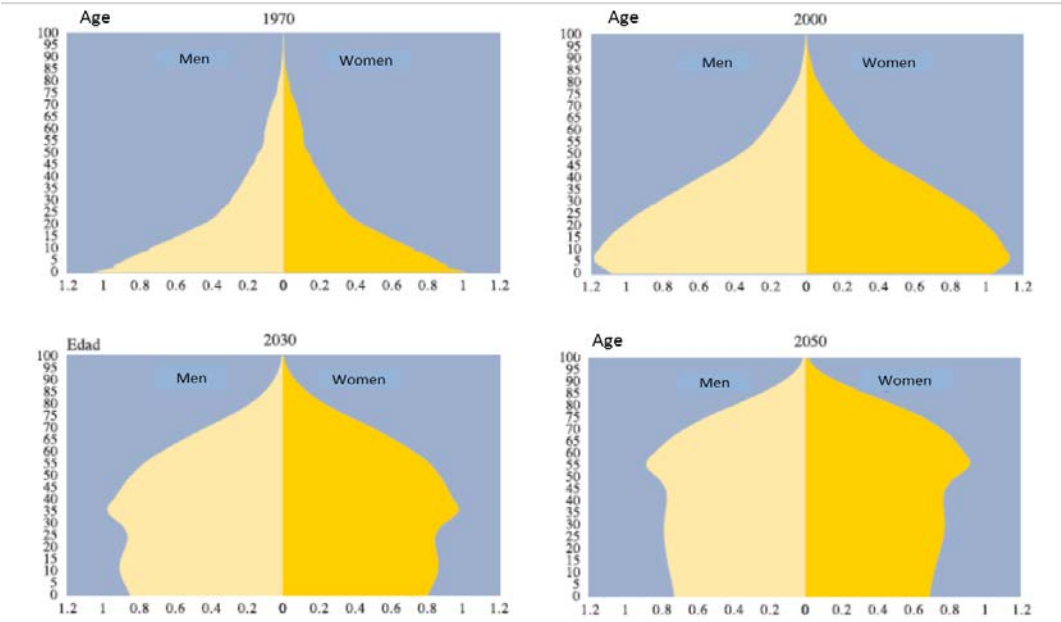
- Increased purchasing power that led to lower cost of processed foods.
- Decrease in physical activity.
- Disinformation about nutritional content of food.
- Consumption patterns of parents are inherited to their children.
- Consumer decisions do not take into account the long-term effects on health.
- The industrial and technological global development, which have led to a more sedentary labor activity.

In addition to this, it is important to highlight the implications of this problem from the economic perspective, because, due to diseases and premature death, increases the need to allocate more spending on health which threaten public and private finances, while reducing the country's productivity due to premature death and the increase in the number of sick people. The last, especially considering that Mexico is experiencing a demographic transition.

According to the last, we can say that obesity has important social implication, because generates high expenses, directly (for those who suffer) and indirectly (to society). These expenses are proportional to the weight excess, which reduces household income and, in general, the life quality of the population.

In this sense, if we consider population trends provided by the National Population Council, (presented in the following graph), clearly there is a concern on current infants and adolescents representing the majority of the population mass in the coming decades. The last implies a urgency in making public policy decisions that take into consideration that the diseases and conditions associated with obesity and overweight are more likely to occur after age 45 and thus, if in the short-run, health problems related to obesity are still a matter of concern within society, we will miss the benefits of a demographic transition with the largest population mass in labor age.

Mexican population pyramids, 1970-2050



Source: CONAPO estimations

a. International experience and economic analysis of the problem

Mexican government uses the OCDE study *"Improving Ufestyfes, tackling obesity: The health and economic impact of prevention strategies"* and analyze various international experiences to identify the different policy alternatives, especially the ones related to limitations in schools on food and beverages of low nutritional value. This, in order to analyze the possibility of implementing several guidelines that allow the establishment of these limitations based on specific criteria, which according to data from the OECD study can generate a 0.70% reduction in the incidence of obesity and the conditions associated with it, as in this document is estimated that the effectiveness of a health education strategy accompany with the introduction of healthy food in cooperatives is -0.2 kg/m2 in Body Mass Index (BMI) of the population in school age so that, considering a BMI 25-35 kg/m2 (including overweight and obesity), one would expect a reduction of 0.60-0.80% in the incidence of obesity.

SEP also uses experiences in countries like German, Argentina, Canada, Spain, United States, France, Japan, Switzerland and Uruguay as reference for the implementation of public policies related to the decrease and control of the obesity problem.

The above is part of a strategy planned to find the main measures that can be adopted to abate the obesity problem in Mexico, which led to the implementation of a strategy of joined action between government and society, established in the sign of a National Agreement for Health Food (ANSA, in Spanish). This Agreement has the following objectives:

1. Encourage physical activity in the scholar, labor, community and recreational environments.
2. Increase the availability, accessibility and consumption of drinking plain water.
3. Decrease consumption and fat in drinks.
4. Increase of the daily intake of fruits and vegetables, legumes, whole grain cereals and fiber by increasing its availability, accessibility and promoting its consumption
5. Improve the ability of making informed diet consumption decisions through a useful and easy to understand labeling, and the promotion of literacy in nutrition and health.
6. Promote and protect exclusive breastfeeding until six months of age, and appropriate complementary feeding from this age.
7. Decrease consumption of sugar and other caloric sweeteners added to foods. This by making accessible reduced food or with no added caloric sweeteners.
8. Reduce daily intake of saturated fat in the diet and minimize trans fats from industrial sources.
9. Provide people with guidance on controlling portion sizes recommended in the preparation of food by making available allowed processed food, and including in restaurants and food establishments, reduced portion sizes.
10. Decrease daily sodium intake by reducing the amount of sodium added and increasing the availability and accessibility of products of low or no sodium content.

As noted, these measures are aimed at changing eating habits among the population in order to reduce caloric intake, as well as to promote greater physical activity that allows the increase of caloric consumption. The last is looking to achieve a better balance reflected into lower prevalence of overweight and obesity in the population.

As part of this range of measures and considering the sharp increase of obesity in youth and infants, it was decided to promote the issuance of a regulation aimed to reduce caloric intake in this population group, at least during school time. To do this, the Ministry of Public Education in joint action with the Ministry of Health proposed the *"General guidelines for the sale or distribution of food and beverages at consumption establishments of basic education campuses"*, where the nutritional characteristics of the food and beverages that can be sold to children into primary and secondary schools are determined, and the sale of products that do not meet those characteristics is restricted. This proposal was submitted for the regulatory revision process to COFEMER along with its Regulatory Impact Assessment (RIA).

From the point of view of the economic theory, was also found that obesity is the result of the interaction of several factors that affect population consumption patterns, so that consumers seemingly take irrational decisions and eat food with low nutritional value despite the effects on their health.

Some of these factors include the lack of complete information for consumers and the existence of self-control problems, besides the presence of externalities. In this sense, it was identified, from the economic theory perspective, the existence of **market failures** and a self-control problem:

1. Consumers do not have all the information about the products they intend to consume, so they cannot know for sure how healthy of harmful may be for them. This situation is only known by producers.

2. The existence of self-control problems may also be a reason for eating food that might not correspond to a rational and not optimal decision, as often happens when there is an addiction problem.

3. The "spillover"[53] effect, which refers to an externality caused by the transmission of habits on the lifestyle of one individual to another. This is the case of parents who teach their children to eat certain food and inherit their consumption patterns.

4. The presence of externalities implies that the optimal consumption for an individual does not correspond with the social optimum.

The constant variable in all cases of election when consumer has not the enough information about the quality of the product is that markets do not work efficiently on their own, which justifies state intervention through mechanisms such as regulation, in this case health regulation.

Also, **obesity and overweight carry on strong externalities such as the high costs generated by medical care, losses in business hours, payments for temporary or**

[53] Suhrcke, M., et al. (2006), Chronic Disease: An Economic Perspective, London, United Kingdom, Oxford Health Alliance.
Becker, G.S., K.M. Murphy (2000), Social Economics: Market Behaviour in a Social Environment, Cambridge, Massachusetts, Harvard University Press.

permanent disability and lost wages and pensions due to premature deaths. This means labor productivity losses, direct costs to businesses and to the public health sector, justifying government intervention.

If we consider access to health as a public good, we can notice that, to the extent in which health care expenditure on problems caused by overweight and obesity restrict the resources that can be used for other diseases and health ailments not related with this preventable problems, it is created a negative externality to the society's health.

From the above we know that we are facing a regulatory problem, but what is its significance? In Mexico and in general, in all the world, the epidemic of obesity is a major problem that affects adults, teenagers and children alike. At the same time, the problem has grown at such a

Consider the case of Mexico, where there is a marked tendency to consume food with low nutritional value, which largely explains the high rates of obesity and overweight described above. So, the spending in low-quality nutritional products is notoriously higher than spending in healthy food. The following table shows clearly how soda consumption may represents more than 300% of expenditure in fruits and vegetables.

Table 1. Expenditure in soda as a proportion of the expenditure in fruits, vegetables and education (%) by income quintiles[54]

Year	Concept	Q1	Q2	Q3	Q4	Q5
2002	Fruits	84%	94%	111%	107%	146%
	Vegetables	348%	315%	331%	252%	224%
	Education	118%	96%	88%	61%	38%
2004	Fruits	84%	80%	104%	126%	121%
	Vegetables	308%	372%	394%	293%	227%
	Education	69%	94%	86%	84%	35%
2005	Fruits	85%	91%	112%	120%	104%
	Vegetables	326%	299%	357%	280%	214%
	Education	111%	170%	86%	53%	32%
2006	Fruits	93%	89%	104%	94%	118%
	Vegetables	303%	321%	320%	265%	222%
	Education	93%	77%	74%	50%	33%
2008	Fruits	81%	95%	92%	100%	82%
	Vegetables	291%	308%	282%	252%	183%
	Education	90%	75%	69%	46%	37%

Source: Own elaboration with data from the ENIGH 2002-2008.

Another major conclusion of this analysis is that lower income families are the ones spending more on food with low nutritional value (in this case soda) as a proportion of what they spend on other important goods and services as fruits, vegetables and education.

[54] The division of population by quintiles refer to a division based on income in five ascending groups, where quintile one represents people who have an income in the range from 0 to 20% lower and so subsequently.

Next we show in more detail the market failures and the self-control problem existing as part of the obesity and overweight problem. There are also presented the regulatory proposals that apply to each case in order to overcome both the market failure and the self-control.

i. Asymmetric information

The existence of a free market implies that everyone has the right to sell and consume any product you want. Nevertheless, the products sold are not always as safety as they should be and the consumer is not aware of the risk he is incurring in.

Information failures	**Disclosure:** Sometimes, producers only provide the information that strengthens their position in the market, rather than sufficient information regarding quality for consumers to make informed decisions.
	Experience goods: These are goods for which consumers cannot evaluate the quality before the purchase, which generates a loss when quality is not the expected.
	Confidence goods: These are goods which quality cannot be verified even after the purchase, since consumers cannot evaluate the consequences.

So that, in the presence of information failures, the consumer has less information about the nutritional quality of the product than the manufacturer.

It should be noted that quality can be classified into two aspects : nutritional quality, which refers to the food suitability to meet the body's needs in terms of energy and nutrients, hygienic quality, concerning the compliance of the product with the specifications or standards aimed at fighting fraud, and ensure the products' safety.

In the case of obesity, food with low nutritional quality in general is sold at low prices, which may lead consumers to prefer this type of food than others with better nutritional quality but at higher price. This, in addition to the information failure, which prevents the consumer to know the quality of the product, leads to a behavior that seems irrational (the product is consumed despite its negative effects on the individuals' health).

Faced with a problem of asymmetric information about the product quality, health regulation can solve this market failure in many ways, such as establishing an obligation on producers to provide more information to consumers, avoiding misleading advertising or establishing labeling easy to understand, as well as establishing educational programs for parents and children to advise them on nutrition.

ii. Externalities

It is said that an externality occurs when the choices of consumption or production of an economic agent (individual, company, government, etc.) affects the utility or the production of another without the permission of this or without compensation. In other words, externalities are those activities that affect others for better or for worse, without paying for them or without being compensated

Externalities	The cost of the individual's behaviors affects others, at least partially (as with social spending to be incurred in the health sector to address the diseases and conditions caused by obesity).

In the case of a negative externality the individual will decide to perform some action beyond the social optimum.

In this situation, a tax that increases prices of food with low nutritional quality will reduce people's consumption of this kind of products harmful to health; as a result, the externalities resulting from overweight and obesity, as well as other chronic diseases attributable to such condition which generate costs to society, will decrease.

At the same time, another solution is given by the Coase Theorem, which is an option that distorts less the market to achieve the social optimum, and points out that the property rights on the generating activity of the negative externality should be attributed to the affected party. Although the last option seems difficult to implement in our case study, as the property rights on a public service, access to health, would be reallocated.

iii. Failures of rationality

Economic theory has also developed different aspects than those based on the paradigm of rationality to explain those individuals' behaviors where a self-control failure seems to dominate.

Rationality failures	Having accurate information about products is not enough to make a good decision on consumption, in this sense: **1)** Consumers may have a self-control problem, which leads to postpone the quality of their health and focuses on the immediate benefits that the consumption of certain good generates them. **2)** Consumers only value the consumption of a type of good rather than their health.

Economic theory in this area concludes that for people who are not aware of their self-control problem, their behavior is reflected in a consumption that only seeks immediate gratification without considering future damage to their health. However, for those people who are aware of this problem, the theory suggests that such individuals, despite being influenced by the desire for immediate gratification, make attempts to have self-control, which at the same time allows them to have healthier behavior in the future.

Health regulation can help to solve rationality failures in consumers, depending on the degree of awareness that consumers have about their self-control problem.

The higher the degree of individuals' awareness about the damage caused to health by consuming products with low nutritional quality, the greater the justification for the State to monitor the proper disposal of information about the risks to consumers.

In the extreme case that consumers are not aware of their self-control problem or this is minimal, as the damage to health by their consumption increases, justification is greater for the State to establish restrictions on such food.

C. Objectives of intervention

In this sense, with ANSA and specifically with the Guidelines for establishing restrictions on food and beverages consumption at school campuses, the objective was to reduce the prevalence and the growth rate of obesity in Mexico, mainly in children.

D. Regulatory alternatives

Based on the identification and characterization of the problem from the empirical and the economic theory point of view, it is observed that, as this is a multifactorial problem, it is required a multiple intervention strategy that addresses all the main factors the cause obesity. For example, in the case of externalities classical interventions are the establishment of taxes, restrictions, transfer schemes of costs or benefits, standards, etc., while for the asymmetric information problem we usually find information and advertising campaigns, labeling rules, sanctions and contracts, among others. Finally, we also have non-regulatory options, such as direct care by a specialized dietitian or prevention through public health campaigns.

For its part, the OECD notes that to address this problem an intervention strategy in four areas must be used:

- Availability of healthy food,
- Access to a healthy diet,
- Knowledge of food,
- Taxes and
- Changing consumer's behavior (more options).

At the same time, these are broken down into the following set of alternatives:

- Physician and dietitian guidance
- Medical advice
- Tax measures
- Regulation of food advertising
- Interventions in workplace
- Food labeling
- Information campaigns
- Self-regulation of food advertising
- Interventions in school campuses

The OECD analysis found that tax measures (taxes on food with low nutritional value and incentives for production and consumption of foods with high nutritional value), interventions in workplace (restrictions) and food labeling have the greatest impact on reductions in health spending associated with obesity and overweight.

In general, better results are obtained when individuals go directly to a doctor or dietitian to address the problem of obesity; however, these policies are not often feasible, mainly because of the cost involved.

Based on this analysis, the OECD promotes a multiple intervention strategy that includes food labeling, tax measures on foods with low nutritional value, self-regulatory schemes for

infant food advertising, programs of health promotion and interventions in school campuses and in workplaces, and individual guidance for people at risk in primary care.

At the same time, it emphasizes that applying the multiple intervention strategy it is estimated that England would benefit most from the package implementation in terms of impact on the health of its population, while Mexico would be the country that would get a higher reduction in the health spending allocated to obesity and overweight.

From the above, COFEMER identified that these alternatives could be included in the following type of measures, in addition to that posed by the authority:

- **Alternative 1:** self-regulation schemes
- **Alternative 2:** Implementation of an Official Mexican Standard applicable to the sale and preparation of food in school campuses.
- **Alternative 3:** Develop an Official Mexican Standard for labeling with provisions applicable to the nutritional information of foods and drinks in general.
- **Alternative 4:** Establish mandatory physical activities that contribute to a lower incidence of obesity or an advertising campaign on the adverse effects of the consumption of certain foods, among others.
- **Alternative 5:** The regulatory proposal by SEP and SSA.

E. Impact evaluation

For the estimate of the impacts, as well as for the quantification of costs and benefits, the measures previously assessed by the OECD, were considered.

Through these interventions society was given more years of healthy life, reducing health care costs. The main objective of prevention is to improve the population health and longevity, and results show that government intervention can be effective.

The general results of the evaluation are:

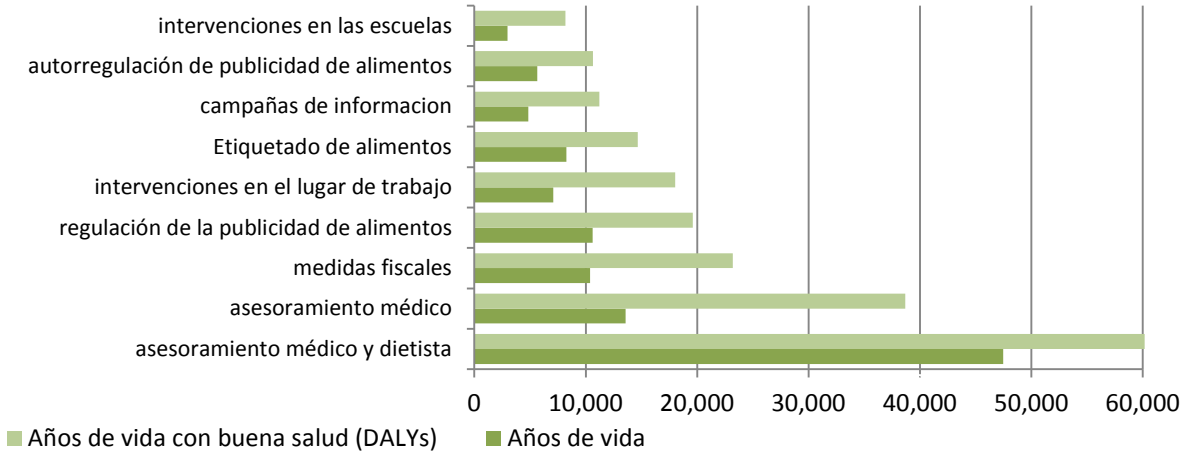
- The original regulation proposal (reducing the "junk food" supply in basic education) is socially and economically efficient, that is, benefits are greater than its costs by approximately 6.36 times. However, these measures have a moderate impact if they are not accompanied by an action plan against obesity in the short term.
- In general, better results are obtained when going directly to a doctor (dietitian) to address the problem of obesity; however, these policies are not often accepted in society, mainly because of the cost involved.

Particularly, the economic evaluation of interventions at the population level (average effect per year) was made through **disability-adjusted life years (DALYs)**, obtaining the following results:

Economic evaluation of interventions at population level (average effect per year)

Intervention	Life years	Years lived in health (DALYs)
Physician and dietitian guidance	47,478	153,118
Medical advice	13,588	38,672
Tax measures	10,385	23,192
Regulation of food advertising	10,610	19,620
Interventions in workplace	7,075	18,016
Labelling of food	8,249	14,680
Information campaigns	4,831	11,206
Self-regulation of food advertising	5,654	10,642
Interventions in school campuses	2,973	8,177

We can see the result of the actions previously evaluated on a graph.



a. Costs and benefits

For the estimation of the previous tables, SEP used the *Chronic Disease Prevention (cdp)* model to calculate the population of children aged 6-14 years to whom the regulation will be directly apply and, on that basis, costs per capita are calculated for disclosure, implementation, evaluation and training considering that the guidelines implementation for the starting year.

Also, the estimate considers the results of the study by (Sassi, Improving Lifestyles, tackling obesity: The health and economic, 2009) and (Sassi, 2010) for calculating the benefits of interventions, expressed as savings in health care spending to treat diseases associated with obesity and overweight, as well as by the increase in productivity related to less premature deaths.

The impact of intervention in school campuses was estimated according to the following scenarios:

- **Baseline scenario:** The reduction in income for the industry (if this does not change its offer) would be marginal, which would result in a cost of 1% of the sales of a quarter, which translates into a total of $51 million pesos. It was also considered that the industry will incur costs for the addition of new products, which were estimated

at 0.5% of the sales value of a quarter, which would mean $25.5 million pesos. The total impact on costs to the industry is estimated at approximately $76.5 million pesos.

- **Moderate scenario:** It is assumed that a 5% reduction in income for each category of cost to industry (products adjustment to the guidelines and products substitution). Under this scenario, estimated losses for the guidelines implementation for the industry would be $509.9 million pesos in the quarter mentioned.
- **Catastrophic scenario:** It was considered that the reduction in incomes for the industry was equivalent to the total value of the sales in school campuses for a semester, reaching a total of $10,197 million pesos. This scenario is unlikely due to the industry adjustments.
- **Threshold scenario:** It considers that the reduction in income for the industry is equivalent to the benefits that society, public sector and the agricultural industry will receive from the guidelines implementation for a period of 100 years. It is a very unrealistic scenario, since it would involve the permanent exit of the industry of consumption establishments of school campuses, as this is not a profitable market.

For the Mexican case a favorable scenario is projected as a result of the implementation of school interventions, which can yield important social benefits due to the reduction in health spending associated with diseases related to obesity and overweight, and to an increased productivity of the labor force, derived from having a healthier population and a greater life expectancy.

In aggregate form, the costs and benefits estimated for the regulation project were the following:

Costs and benefits of the regulation project "General guidelines for the sale or distribution of food and beverages in consumption establishments of basic education campuses"

Concept	Projected amount (million pesos 2008)
COSTS	
I. Cost in competitiveness for industrialized food production businesses	
Cost of adjustment of processes to comply with guidelines	$ 51.00
Loss of Jobs	Not applicable
II. Cost in efficient functioning of the industrialized food market	
Gradual substitution of products	$ 25.50
III. Cost of guidelines implementation	
Diffusion, implementation and evaluation	$ 6,332.00
Training personnel from consumption establishments of basic education campuses	$126.00
Total costs (I+II+III)	**$ 6,458.00**
BENEFITS: Benefits on health per reduction in overweight and obesity resulting from the guidelines implementation	
IV. Direct benefit per medical care	$ 13,743.00
V. Indirect benefit per productivity	$ 16,462.00
VI. Indirect benefit per increased sales of fruits and vegetables	$ 12,889.00
Total benefits **(IV+V+VI)**	**$ 43,094.00**
CBR	**6.67**
BENEFITS - COSTS	**$ 36,636.00**

Source: (COFEMER, 2012)

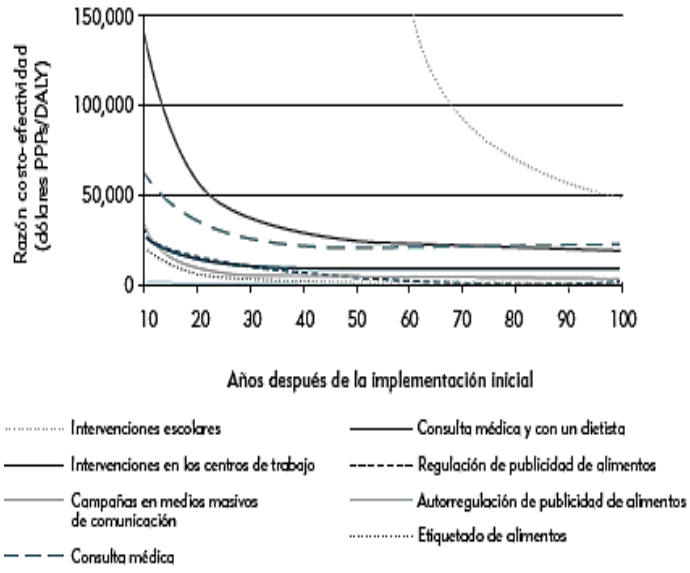
b. Cost-effectiveness ratio

As a complement, the results of Sassi (2010) were used to identify the impact of the measures through the years of healthy life obtained; this was reflected in the following Cost-Effectiveness ratio:

$$CER = \frac{Cost}{DALY} = "x"$$

So that “x” will be the cost per each disability-adjusted life year.

Graph 1: Cost-effectiveness ratio of implemented measures



Results clearly show the potential benefits of the different measures that can be taken at government and private levels, to address the problem of obesity; however, public policy decisions should also consider the costs of its implementation, which has been recently analyzed by the OECD as well, in terms of the cost-effectiveness ratio of various preventive actions.

In Mexico, the cost-effectiveness analysis of the implemented measures is shown in the graph, which presents all the measures analyzed over time, showing a reduction of the cost-effectiveness ratio over time for all cases.

Finally, the study by (Sassi, 2010) incorporates the impact of estimated health benefits of multiple intervention strategy. Such analysis was of great importance when deciding the number of actions that would make up the regulation project.

The baseline analysis estimated that the United Kingdom would be the country that would benefit most from the implementation of the package in terms of impact on its population health, while Mexico would be the country that would get a greater reduction in health spending allocated to obesity and overweight.

F. Choosing the best regulatory alternative

In this case it was not considered to make the analysis of each regulation alternative. So, the process and choice of the alternative involved determining what would be the

appropriate regulatory actions within one single alternative that, supported by a regulatory framework, complies with the objective of reducing the problem of childhood obesity in Mexico.

From the actions previously shown and evaluated, considering the impact they could have on the national economy, the Program of Action in the School Context only considered the following:

- Health education though activities for schoolchildren, which promote the comprehensive training process by emphasizing individual, family and community health care, so it is expected that such educational activities transcend the school context.

- The second component related to promoting regular physical activity at school and outside, seeks the schoolchildren adoption of active lifestyles, and

- Finally, the third component is focused on generating healthy school environments, that is, create a school environment where children and adolescents learn to make informed decisions about what is beneficial to their health.

Particularly, the measures inherent to the three axes previously exposed are: front labeling that facilitates decision-making to consumers (encouraged by the SE and COFEPRIS), strengthening regulation in advertising, particularly that addressed to children (which has been started through the Self-regulation Code of food and non-alcoholic beverages advertising addressed to children, PABI Code, by PROFECO and COFEPRIS), workplace interventions (encouraged by the STPS) and educational campaigns in media encouraged by the Health Sector (IMSS, ISSSTE, PEMEX, SEDENA, SEMAR and DIF).

G. Final remarks

The regulation project opened the space to generate different studies regarding particular products, that is, soft drinks. These studies considered impacts not only on the individuals' health, but on income, spending and individuals preferences, extending the analysis for future considerations. Currently, both the labeling and tax measures are being debated in the Congress by the legislators of the country.

In addition it was required a solid theoretical framework that supported the proposed regulation. The theoretical model explains how individuals rationally decide to consume food with low nutritional level, under the approach of the Optimal Control Theory. This model obtains the optimal trajectory of the individual health state, properly selecting food intake with low nutrient level that maximizes the aggregate utility that provides complete diet, adjusted by an intertemporal discount rate and life expectancy.

The model incorporates a price-preference ratio, between food with low nutritional level and healthy food. In this model it is assumed that food with low nutrient level tastes better and is purchased at a price lower than healthy food.

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I. Problems the regulator faced when evaluating the regulatory impact

The quantification in this regulation project presented three essential challenges:

- The regulatory alternative involved the quantification of different actions; hence, the identification of costs and benefits was a complex process that considered many opinions of the regulated sector to identify all the costs.
- The methodologies and values of international studies helped to identify the regulatory alternatives. However, the lack of data led the estimate to miss the monetary quantification of different costs and benefits to strengthen the CBA; for example, Mexico lacks a VSLY which may assign value to DALY's.
- The management of the pressure from those involved in the process was a challenge for the government agency. In this regard, the private sector was represented by large and solid enterprises which incomes were affected.