AB Baseline measurement for The Department of Health

Report on part I of the baseline measurement of the administrative burden from the Department of Health

Report v Dec 12

December 6th, 2012

An Roinn Sláinte
DEPARTMENT OF HEALTH

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1 Introduction

In 2007 the European Commission launched its Action Programme on Reducing Administrative Burdens (AB), setting a 25% target to reduce administrative burden for businesses arising from European legislation by 2012. The Irish government set its own 25% target in March 2008 to reduce the administrative burden for businesses by 2012.

In order to be able to reduce the administrative burden it is necessary to determine the baseline level. The Irish government decided that a baseline measurement of the administrative burden for businesses must therefore be carried out. This baseline measurement should determine the administrative burden of Irish legislation in 2008 using the method of the Standard Cost Model.

Experiences with baseline measurements of the administrative burden in other countries have shown that 90% of the administrative burden results from only 5% of the information obligations* in the legislation. Based on this the Irish government decided to carry out the baseline measurement for those information obligations that cause the most administrative burden. These information obligations were selected from the legislation of eight government departments[1] and Revenue by representatives of the departments and were then verified by businesses. In total 170 information obligations (IO's) were selected. (*obligations to provide information to the government about activities and behaviour)

The main goal of the AB baseline measurement is to measure the administrative burden for the 170 selected information obligations. Therefore a number of business interviews were conducted to establish the average cost and length of time it takes a typical business to comply with a given information obligation. The procedure of complying is described and quantified in the standard cost model by multiplying the average administrative burden (P) and the number of businesses that have to comply (Q). The results of the measurement are discussed with the relevant government bodies, businesses and business associations (see for annex II for the list of organisations involved in the measurement).

This baseline measurement is part of the simplification programme that this department is engaged in in order to reduce the administrative burden for businesses by 25%.

In this report the AB baseline measurement for information obligations of the Department of Health is described. The first chapter of this report contains background information and sets out the goals of the project. In the second chapter it is explained how the measurement has been carried out and how the information was gathered in interviews with government experts and businesses. The information obligations that were measured for this department and the relevant target groups are described in chapter 3. Chapter 4 shows the results of the baseline measurement for 2008 and 2011. The reduction suggestions obtained and progress on these are discussed in chapter 5. Chapter 6 presents a summary of the measurement results for the Department of Health.

[1] Department of Communications, Energy and Natural Resources, Department of Social Protection, Department of Agriculture, Food and the Marine, Department of Transport, Tourism and Sport, Department of Finance, Department of Environment, Community and Local Government, Department of Jobs, Enterprise and Innovation and the Department of Health.

2 Measurement process

2.1 The AB reduction project

The baseline measurement of the administrative burden for the Department of Health is part of a larger project to determine the baseline of the administrative burden for all Irish legislation and to make simplification plans to reduce this burden by 25%. This project is illustrated in the figure below.

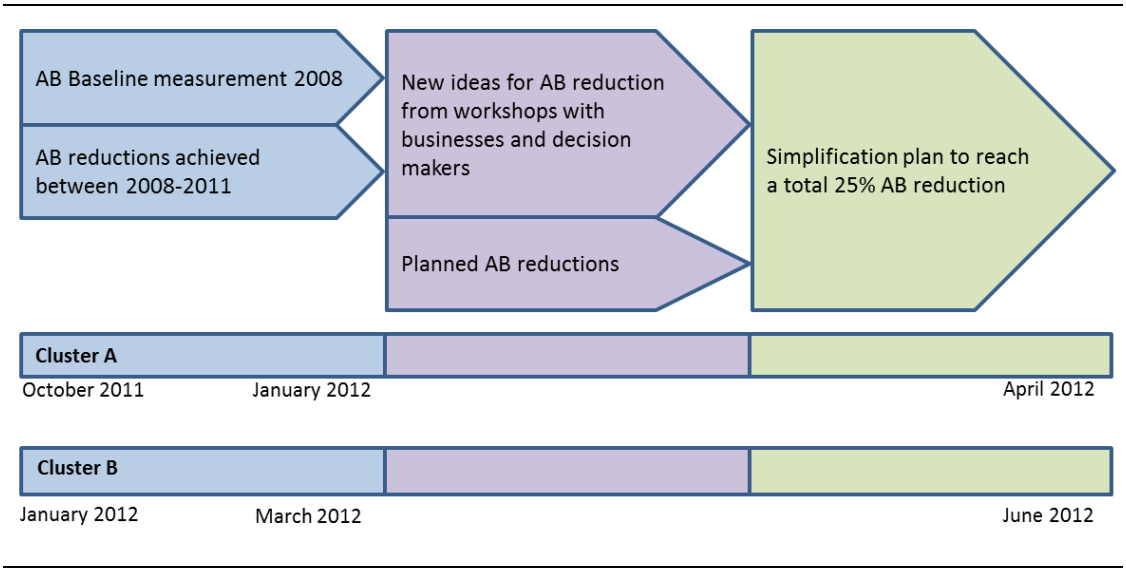

Figure 1. Illustration of the AB baseline measurement project of the Irish government.

The baseline measurement was carried out by measuring the AB of 170 IO's from 7 departments and The Department of Health, which are assumed to cause the largest AB for businesses in Ireland. The baseline measurement was carried out in two clusters[2]. Cluster A started in October 2011 and cluster B in January 2012. In each department, the baseline of the AB was measured based on the legislation in effect on the 31st of December 2008. This reference date was determined by the Irish government. The reduction target of 25% will be measured against the AB on this date. The total 25% AB reduction consists of:

- The AB reductions already achieved since 2008. During the baseline measurement the changes in the IO's since 2008 were determined. With these changes the achieved reduction between 2008 and 2011 was calculated.
- The AB reductions already planned but not yet implemented. These reductions will be achieved after 2011 and are not part of the baseline measurement project.
- New ideas for AB reduction. To complete the 25% reduction, new ideas should be formulated to further reduce the AB. These ideas will be identified in workshops with businesses and decision makers from the Irish government.

[2] Cluster A: Revenue, Department of Communications, Energy and Natural Resources and Department of Social Protection, Cluster B: Department of Finance, Department of Agriculture, Food & the Marine, Department of the Environment, Community & Local Government, Department of Transport and Department of Health.

2.2 Definitions and the Standard Cost Model

In order to safeguard public interests, governments impose various measures on businesses obliging them to carry out or avoid certain activities or behaviour. Complying with obligations takes time and can involve costs. In the figure below an overview is given of the different kinds of costs businesses incur from complying with government obligations.

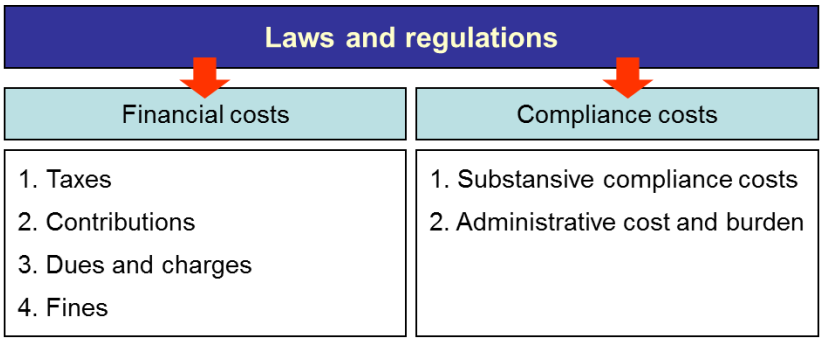

Figure 2. Different types of costs resulting from government obligations.

The administrative burden results from obligations to provide information to the government about activities and behaviour. These obligations are called 'information obligations'. The administrative burden is defined as:

The administrative burden is the cost for businesses for complying with information obligations resulting from Government imposed legislation and regulations.

The administrative burden is a subset of the administrative costs. The administrative costs also encompass administrative activities that businesses will continue to conduct if the regulations were removed. The administrative burden is the part of the administrative costs that businesses sustain simply because it is a regulatory requirement. If an activity will still be carried out if the obligation is abolished, this is not part of the administrative burden but of the administrative costs.

The Standard Cost Model

Administrative Burden is calculated by using the Standard Cost Model (SCM). The SCM makes it possible to:

- Obtain detailed insight into the AB per information obligation or Act.
- Obtain insight into the starting points and basic data of the AB calculation, thereby enabling the (effects of) reduction proposals to be properly quantified.
- Calculate the costs of alternatives to intended legislation and regulations, and their effects.
- Draw up fast, reliable reports on the development of the AB during the course of a government term.

The data used in the SCM to calculate the AB is always retraceable to its sources. This makes the calculation of the AB transparent. This is important because:

- In the future changes will be made to the information obligations in order to reduce the administrative burden. In order to make the calculation of these reductions as reliable as possible, it is important to know which sources were used.
- If questions are asked about the way calculations were made, it is necessary to know the source of the information.

The baseline measurement of the administrative burden is done in four steps. These steps are shown in the figure below. The amount of interviews is specific for the Department of Health.

	Measurement step	Project activities
1	Investigate the IO's (mapping)	For each IO the relevant information was gathered. For instance the applicable legislation and the forms used.
2	Interview government experts	8 interviews were held with government experts to verify and complete the information from step 1.
3	Interview businesses	16 interviews were held with businesses to gather information about the time and costs to comply with the IO's.
4	Calculate and report the AB	The information was entered in the SCM to calculate the AB. The results were described in this report.

Figure 3. The four steps in the baseline measurement.

3 Information obligations and target groups

3.1 Information obligations

For The Department of Health, nine information obligations (IO's) were selected to be measured. In this baseline measurement for all of these information obligations the administrative burden were calculated. The table below gives an overview of the number of information obligations measured. In annex I of this report the complete list of information obligations for the Department of Health is given. This list includes a short description of each information obligation.

Table 1. Information obligations in the measurement.

Nr.	Information obligation	Information obligations	
		Measured	Not measured
1	Private nursing homes - Registration	X	
2	Private nursing homes - Payment of annual fee	X	
3	Private nursing homes - Inspection	X	
4	Pharmacy - Registration of pharmacies	X	
5	Pharmacy - Records for controlled substances	X	
6	Pharmacy - Registration of individual pharmacists	X	
7	Foodstuff - Hygiene requirements *	X	
8	Foodstuff -Notification of new establishment	X	
9	Foodstuff -Traceability requirements *	X	
	Total	**9**	**0**

* See sections 4.3

3.2 Target groups

In the baseline measurement for each IO the number of businesses that have to comply were determined by using government databases or estimated by government experts. These numbers are listed in the SCM including the source from where the numbers were derived. The table below shows the target groups that have to comply for the most relevant IO's of this department. For each target group the number of businesses within that target group is mentioned for the reference year of the baseline measurement (2008).

Table 2. Target groups of the IO's for the Department of Health

Target group	Description	Number of businesses (2008)
TG1	Private nursing homes	451*
TG2	Retail pharmacy businesses	1,608
TG3	Individual pharmacists	4,465
TG4	Food business establishments HSE official control or supervision	43,926

* All nursing homes- private, public and voluntary- must comply with registration and inspection requirements.

4 Administrative Burden

4.1 Administrative Burden for 2008

The measured administrative burden for the selected information obligations for the Department of Health for 2008 is approximately € 381 million per year. The figure below illustrates this per IO.

Table 3. Administrative burden for 2008 per information obligation

Number	Information obligation	Administrative Burden in € per year
1	Private nursing homes - Registration	1,633,200**
2	Private nursing homes - Payment of annual fee	20,900
3	Private nursing homes - Inspection	494,900
4	Pharmacy - Registration of pharmacies	286,500
5	Pharmacy - Records for controlled substances	3,449,200
6	Pharmacy - Registration of individual pharmacists	280,800
7	Foodstuff - Hygiene requirements *	300,582,900 *
8	Foodstuff -Notification of new establishment	47,600
9	Foodstuff -Traceability requirements *	73,897,300 *
	Total administrative burden in 2008	**380,693,300**

* See section 4.3.

** Note the new legislation for nursing homes only came into effect on 1st July, 2009.

The information obligations causing the highest administrative burden are:

1. IO 7, the hygiene requirements for foodstuff, causes a € 301 million administrative burden per year. This is 79% of the total measured administrative burden for the Department of Health. The reason for this high burden is a combination of three factors:
   a. A large number of businesses must comply with the system.
   b. The administration takes up a relatively large amount of time.
   c. The activities need to be executed multiple times daily.

   Keeping records of the way hygiene is managed, mostly using the HACCP standards, is the most burdensome part of the system.
2. IO 9, traceability requirements, causes a € 74 million administrative burden per year. This is 19% of the total measured administrative burden for the Department of Health. The combination of a large amount of businesses and a high frequency leads to a high administrative burden. The time needed to maintain a system of documentary evidence of compliance with traceability and the associated completion of records contributes most to the total administrative burden.
3. IO 5, the keeping of records for controlled substances by pharmacists, causes a € 3.5 million administrative burden per year. This is less than 1% of the total measured administrative burden for the Department of Health. The reason for this high burden is the high frequency. Pharmacists need to update their records multiple times per week or even per day.

4.2 Administrative Burden for 2011

The measured administrative burden for the selected information obligations for the Department of Health has not changed since 2008. The administrative burden for 2011 is approximately € 381 million per year. The figure below illustrates this per information obligation.

Table 4. Administrative burden for 2011 per information obligation

Number	Information obligation	Administrative Burden in € per year	Administrative Burden in € per year
1	Private nursing homes - Registration	1,633,200	1,633,200
2	Private nursing homes - Payment of annual fee	20,900	20,900
3	Private nursing homes - Inspection	494,900	494,900
4	Pharmacy - Registration of pharmacies	286,500	286,500
5	Pharmacy - Records for controlled substances	3,449,200	3,449,200
6	Pharmacy - Registration of individual pharmacists	280,800	280,800
7	Foodstuff - Hygiene requirements	300,582,900 *	*
8	Foodstuff -Notification of new establishment	47,600	47,600
9	Foodstuff -Traceability requirements	73,897,300 *	*
	Total administrative burden in 2011	**380,693,300**	**6,213,100**

* See section 4.3

Three information obligations, numbers 7, 9 and 5, contribute to over 99% of the total administrative burden.

4.3 Department's Simplification Programme

The legislation associated with the burden arises in the main for the purpose of ensuring public health and patient safety. In respect of nursing homes the legislation was only introduced in 2009 in response to grave concerns for the safety and welfare of residents following certain well publicised incidents and involves a 3-year registration cycle which has only just been completed. Reductions in resultant burdens are projected as the new regulations are bedded down in subsequent cycles. The Department plans to address certain reduction proposals identified during the measurement exercise and will continue to liaise with stakeholders on an ongoing basis to identify further potential burden reduction measures.

* The legislation requiring compliance with hygiene and traceability requirements by food business operators arise as a result of EU Regulations which are directly applicable in each Member State. It has been decided to not retain the related Information Obligations in the Department's Simplification Programme as the Statutory Instruments giving force to the relevant EU Regulations add no further administrative burden. Compliance with the aims of this legislation is necessary from food business operators to ensure no adverse public health incidents which might also otherwise impact negatively on what is one of the largest industries within this economy. Nonetheless, the Department of Health and the Food Safety Authority of Ireland (FSAI) will examine the reduction suggestions and comments identified by businesses in respect of the hygiene and traceability Information Obligations during the measurement exercise and will continue to liaise with stakeholders on these issues. (see also Foodstuff section 5.3.3 on pages 15 -16).

5 AB reductions

5.1 Reductions achieved

The administrative burden of The Department of Health has not changed from 2008 to 2011. The total administrative burden is €6.2 million per year across the 7 Information Obligations that are to be addressed within the Department's Simplification Programme.

5.2 Planned further reductions

The Department of Health has not yet agreed upon plans to reduce the administrative burden for businesses. Therefore no level of reductions can be calculated for now. However the Department plans to assess the reduction suggestions identified during the measurement exercise and will continue to liaise with stakeholders on an ongoing basis to identify further potential burden reduction measures. The main reduction suggestions received are outlined in section 5.3.

5.3 New suggestions for AB reduction

During the baseline measurement new suggestions to reduce the administrative burden have been made in the interviews with businesses and government experts. The feasibility of the suggestions from businesses has not been assessed during the measurement project. The main suggestions from businesses are set out below. Also provided are the initial responses of the government experts on those suggestions.

In addition some businesses have provided comment (as separate from reduction suggestions) on the legislation and how it is enforced. Those comments have been forwarded to the relevant department officials and agencies for appropriate attention.

1. Private nursing homes

The relevant legislation in respect of which the measurement was carried out did not come into effect until 1st July, 2009 and applies to all nursing homes, private, voluntary and public. That legislation includes:

- Parts 8 and 9 of Health Act 2007,
- Health Act 2007 (Care & Welfare of Residents in Designated Centres for Older People) Regulations 2009 (S.I. No. 236 of 2009) as amended,
- Health Act 2007 (Registration of designated centres for older people) Regulations 2009 (S.I. No. 245 of 2009) as amended.

It is the Department's view that this legislation, which has introduced a new system of regulation in this sector, has required all involved, regulators and nursing homes alike, to engage in new procedures designed to provide quality and safety of service for nursing home residents. It is to be expected, in the initial registration cycle and inspections introduced in this legislation, that the time required for nursing home management to become familiar with the new regime and associated administrative requirements will mean that the Administrative Burden will be at a level significantly higher than could be expected to exist if the measurement were to be carried out when all have been through the cycle at least once. It should also be recognised that certain external costs will not be incurred in subsequent cycles. While accepting that the initial compilation and collation of certain documents (guidelines, procedures manuals, etc.) is time-consuming, once completed these need only be updated as required, considerably reducing the Administrative Burden.

Registration of private nursing homes.

The Health Information and Quality Authority (HIQA) has just completed the first 3-year cycle of registration and inspection at end June 2012, and will evaluate the process with a view to considering how procedures could be further simplified for the benefit of both providers and themselves as regulator. It is currently developing a more streamlined renewal process. It is believed the Administrative Burden will reduce as all become more familiar with the process in future cycles. Some simplification suggestions may have to be examined in the context of a review of the Health Act 2007 (Registration of Designated Centres for Older People) Regulations 2009.

The following suggestions were made:

a. **Prepopulate forms**. The Health Information and Quality Authority (HIQA) should assign a unique registration number to each designated centre and associate with that number the information provided about that centre that remains constant, e.g. name, address, contact details, operator and bed numbers. Using this registration number, it should be possible to prepopulate all future forms. Operators could then amend as required should a change occur.

b. **Use online forms**. It would be convenient if software or online templates would be available for the more standard documentation e.g. Statement of purpose. It would also be useful if the HIQA could provide online access to its database so that the operator can update the required documentation online rather than via paper submission.

c. **Accept documentation in an electronic format**. The costs of printing out the significant documentation gives rise to considerable expenses in terms of ink and paper alone. If the HIQA would accept the documentation in electronic format, this would reduce the administrative burden.

Response *- The HIQA has stated that it would be open to suggestions in relation to operational matters such as the use of on-line forms and other electronic means to streamline the registration process. As of now, its IT systems are not capable of this; it is, however, hoped to upgrade the IT systems over the next couple of years with a view to accepting electronically transmitted information. HIQA is prepared to consider options such as the possibility of accepting declarations to the effect that information previously supplied has not changed in the interim with service providers.*

d. **Avoid seeking unnecessary or duplicate information**. Businesses feel some information asked for is not necessary for administrative purposes. The following examples are given:

   i. Only one form of ID should be required in respect of the person-in-charge. Now both birth certificate and ID with photo needs to be available (under "Documentation required to be enclosed" section of Registration Application).

   ii. The requirements for staff histories and past employer references for long-term senior staff are too rigid. Getting this information can be hard for this group, as previous employers may no longer in business or previous posts might have been abroad.

   iii. The standards set for references in respect of non person-in-charge staff could be examined as it is considered onerous and provides little information considered to be of benefit to the HIQA.

iv. The requirement for members of the management team to have Garda vetting and also to supply a declaration form signed by a solicitor, is considered as a duplication of effort.

***Response** - HIQA has advised that the suggestion of only asking for one form of ID for the person-in-charge could certainly be considered. Other requirements, however, such as staff histories and references are considered necessary in order to protect and safeguard nursing home residents.*

e. **Share information between government bodies**. Much of the information provided to the NTPF for Nursing Home Support Scheme (Fair Deal) is also requested by the HIQA. If this information could be shared between Government agencies, the AB on operators would be reduced because it wouldn't be necessary to provide the information to both bodies separately. Other public bodies requiring information are the Environmental Health Offices, Revenue, Valuation Office (rates), Health and Safety Authority, Social Welfare and NERA.

***Response** - This suggestion would have to be considered in the context of data protection, independence of statutory bodies, etc.*

Inspection of private nursing homes.

a. **Avoid requesting any information already available to the HIQA.** The need to present at/in advance of inspection documentation already provided with the registration pack is considered a duplication and unnecessary. Also, much of the documentation required to be present for inspection by the HIQA is already covered by employment, health & safety or other such legislation.

***Response** - During an inspection, HIQA inspectors are, among other things, checking to make sure that copies of documentation, e.g. statement of purpose and other required policy documents are actually available on the premises. A critical issue when the primary legislation (Health Act 2007) was drawn up was that comprehensive information would be readily available, including to residents and their relatives, on services provided in nursing homes.*

b. **Make sample documentation available**. If the HIQA could make available an approved sample of documentation to be inspected, the centres could replicate these. Thereby avoiding the need to rewrite such documentation. It would also be useful if a standard approach on the composition of a Statement of Purpose could be agreed upon with operators. In the current situation the decision if the approach is acceptable is considered subjective depending on the inspector.

***Response** - This refers to the provision of standardised Statements of Purpose and other policies and protocols required under the legislation. HIQA is of the view that each home is an individual unit, with specific management requirements - one size does not fit all. The onus is on providers and persons-in-charge to demonstrate that they are capable of operating a nursing home. Hence, HIQA do not provide sample policy documents.*

2. Pharmacies

In relation to the registration process, remove a number of out of date requirements in relation to the inspection process and streamline some other procedures.

Response - *The PSI has already undertaken a review of the documentation used for registration and made a number of changes aimed at reducing the time required to complete the application. A new information pack has also been designed to assist with the inspection process.*

In relation to the recording requirements for controlled drugs, examine the possibility of introducing an electronic recording system, taking account of the safety requirements for this class of drugs.

Response - *The PSI has made an initial examination of the recommendation and notes that existing software systems could be utilised to deliver a controlled drugs register in electronic format. However any such system would have to be independently validated and certified. It has not been possible to cost this as yet. The Department would also have to amend the legislation accordingly to provide for this. Further examination of this recommendation will be necessary.*

3. Foodstuff

<u>Notification of a new establishment.</u>

a. **Provide the form online.** At this moment, the form for notifying the start of a new establishment must be requested from the local Environmental Health Officer (HEO). It would be useful if the form would be available online. It would also be useful if the form could be submitted online.

b. **Permit central notification.** Some establishments are part of a chain. It would be useful if a central notification for multiple sites nationwide rather than by region would be available. It would also be useful if a notification of multiple sites in the same region on a single form would be permitted.

c. **Make EHO contact details available on the Food Safety Authority of Ireland (FSAI) website.** The Health Service Executive (HSE) website is not seen as a logical location for many potential operators.

Response - *The FSAI have advised that the HSE will be improving this process by means of an on-line registration facility and also by allowing multi-unit operators to register only once.*

<u>Hygiene requirements.</u>

a. **Accept automated data logs and the use of digital probes on temperature control**. In retail establishments the printouts from an automated temperature control system to monitor all refrigeration are not acceptable to an EHO as records to demonstrate compliance. EHO only accepts manual recording, even though this is only a transcript of the automated logs. EHO also does not accept the use of digital probe.

b. **Make more distinction between critical and non-critical areas.** Reduce the need for non-critical areas to be as stringently assessed as the more critical areas. For example, documenting

the cleaning regime for toilets for public use in-store – it will be obvious if they are cleaned or not – the completion of paperwork will not improve their cleanliness.

c. **Shorten the retaining period for records.** The length of time records are expected to be retained is considered to extensive, particularly for fresh produce. Storage costs for these archives can be high.

Traceability requirements.

a. **Shorten the retaining period for records.** The length of time records are expected to be retained is considered to extensive, particularly for fresh produce. Storage costs for these archives can be high.

b. **Introduce support for labelling.** Labelling requirements are considered onerous, particularly by Small and Medium Enterprises (SME's). There is a potential for FSAI to provide further assistance or a support network to businesses to ensure labels meet legislative requirements – if possible on a case-by-case basis. This lack of support is stopping SME's from accessing wider markets as distribution businesses require the producer to comply; otherwise they cannot carry their products.

As previously set out in section 4.3, it has been decided to not retain Food Hygiene and Traceability Information Obligations in the Department's Simplification Programme. Each EU Member State (through its competent authority) must ensure compliance with the EU Regulations under which these obligations arise as EU Regulations are directly binding. Therefore Member States have little or no scope to reduce administrative costs which arise from complying with those Regulations. The Statutory Instruments giving force to the relevant EU Regulations add no further administrative burden.

This decision also takes into account that the FSAI has provided comprehensive guidance measures to businesses based on the requirements of those EU Regulations. The UK competent authority measured the impact of similar guidance it had provided to UK business as providing a reduction of 60% on the administrative burden attaching to implementing HACCP systems. It is also noteworthy that many larger businesses, particularly in the manufacturing and distribution sectors, choose to introduce measures in respect of hygiene that exceed the obligations placed by legislation for reasons of competitive advantage or to meet particular customer requirements.

The Department of Health and the FSAI will examine and take account of the reduction suggestions and comments identified by businesses to ensure no unnecessary administrative burden is placed on business and will continue to work with food business operators to prevent adverse public health incidents which might also otherwise impact negatively on what is one of the largest industries within this economy.

6 Summary

1 For the Department of Health, nine information obligations have been measured. The administrative burdens for businesses that result from these information obligations in 2008 are approximately €381 million per year. This is mainly caused by the following information obligations:

- Hygiene requirements for foodstuff (€301 million per year). This burden is imposed on the 43,926 businesses in the foodstuff sector.
- Traceability requirements for foodstuff (€74 million per year). As with hygiene requirements, this burden is imposed on the 43,926 businesses in the foodstuff sector.
  - Note. As is set out in Sections 4.3 (page 11) and 5.3.3 (page 15) it is not proposed to retain the above two food IOs in the Departments Simplification Programme as the Statutory Instruments giving force to the relevant EU Regulations add no further administrative burden. The seven information obligations which will be addressed in the Departments Simplification Programme account for €6.2 million in administrative burdens for businesses.
- Records for controlled substances (€3.5 million per year). This burden is imposed on 1,608 retail pharmacy businesses.

2 The Department of Health has not made changes to reduce the administrative burden for businesses between 2008 and 2011. As a consequence the administrative burden for businesses in 2011 remains approximately €6.2 million.

3 At the moment of the measurement, the Department of Health has not yet agreed upon measures to reduce the AB for businesses. The Department continues to examine the suggestions received as part of its Simplification Programme.

Annex I. List of information obligations

The table below gives an overview of the information obligations selected for the administrative burden baseline measurement.

Table 5. Information obligations in the measurement.

Nr.	Legislation reference	Information Obligation
1	Health Act 2007. Health Act 2007 (Registration of designated centres for older people) Regulations. Health Act 2007 (Care and welfare of residents in designated centres for older people) Regulations.	Private nursing homes - Registration. Under the Regulation of Designated Centres, each private nursing home needs to be registered every 3 years. The registration process contributes to an administrative burden.
2	Health Act 2007. Health Act 2007 (Registration of designated centres for older people) Regulations.	Private nursing homes - Payment of annual fee. Each private nursing home needs to pay an annual fee based on the number of residents or places available. Payment is made three times per annum. Determining and transferring the fee requires administrative activities, causes an administrative burden.
3	Health Act 2007 and Health Act 2007 (Care & Welfare of Residents in Designated Centres for Older People) Regulations	Private nursing homes - Inspection. In order to verify if private nursing homes comply with the applicable legislation, each facility is visited for an inspection at least once every three years. The time consumed in preparation for and during the inspection is considered an administrative burden.
4	Pharmacy Act 2007	Pharmacy - Registration of pharmacies. Each pharmacy needs to be registered annually. It is also necessary to give a notification if registration details change. The registration process takes time and therefore causes an administrative burden.
5	Misuse of Drugs Act 1977	Pharmacy - Records for controlled substances. Certain of the substances provided by pharmacies are controlled by the Pharmaceutical Society of Ireland. Each provision of one of these substances must be recorded in a register and therefore causes an administrative burden.
6	Pharmacy Act 2007	Pharmacy - Registration of individual pharmacists. All pharmacists are required to register with the Pharmaceutical Society of Ireland, which is the body responsible for regulating the profession in Ireland. This registration has to be renewed annually. It is not possible to practice pharmacy in Ireland without being registered.
7	S.I. No. 369 of 2006 European Communities (Hygiene of Foodstuffs) Regulations 2006	Foodstuff - Hygiene requirements. These Regulations impose obligations on food business operators in respect of the hygiene of foodstuffs including the general hygiene requirements. Most businesses use the HACCP standards (Hazard Analysis and Critical Control Point) for complying with these regulations. The keeping of a system of documentation and records takes time and therefore causes an administrative burden.

Nr.	Legislation reference	Information Obligation
8	S.I. No. 369 of 2006 European Communities (Hygiene of Foodstuffs) Regulations 2006	Foodstuff -Notification of new establishment. Each new establishment in the foodstuff sector needs to notify the local authority before starting business. The time spent in making a notification is considered an administrative burden.
9	S.I. No. 747 of 2007 European Communities (General Food Law) Regulations 2007	Foodstuff -Traceability requirements. These Regulations require businesses in the foodstuff sector to have traceability systems and procedures (including records) in place to ensure that they can trace foodstuffs "one step forward and one step back" throughout the food chain. The keeping a system of documentation and records takes time and therefore causes an administrative burden.

Annex II. Organisations involved in the baseline measurement

The table below gives an overview of the organizations involved in the measurement of the administrative burden for the Department of Health.

Table 6. Organisations involved in the baseline measurement.

Organisation	Name
BRU	Don O'Connor Eric Giguère
The Department of Health	Michael Burke Paul Brosnan
Business representatives	Chambers Ireland Irish Farmers Association Nursing Homes Ireland Restaurant Association of Ireland

The business representatives did not participate in the measurement itself but they were consulted during the project about the measurement process and methodology.