Summary: Intervention & Options Department /Agency: Title: Department for Business, Impact Assessment of Aerosol Dispensers Regulations 2009 2009 Stage: FINAL Version: FINAL Date: 20 October 2009 Related Publications: Consultation on a European Commission proposal to adapt the ADD (Aerosol Dispensers Directive) 75/324/EEC to technical progress.

Available to view or download at:

http://www.berr.gov.uk/files/file3259

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What is the problem under consideration? Why is government intervention necessary?

The UK has to implement Commission Directive 2008/47/EC of 8 April 2008 which adapts the 1975 ADD (Aerosol Dispensers Directive) to technical progress. Member States must adopt domestic regulations implementing the Directive by 29th October 2009 and the provisions must come into force from 29th April 2010. The UK plans to implement the provisions by revoking the old regulations - SI 1977/1140 Aerosol Dispensers (EEC Requirements) Regulations - and remaking new regulations. The new regulations will improve both the level of safety and consumer information with effect from 29th April 2010.

What are the policy objectives and the intended effects?

The objective is to update aerosols legislation in line with modern international practice, based on UN recommendations and updated transport legislation.

The intended effects are to protect the consumer and ensure the safety of aerosol dispensers.

What policy options have been considered? Please justify any preferred option.

The following options have been considered:

(i) do nothing, in which case the UK would not meet its EU obligations and the level of consumer safety of aerosols would be compromised;

(ii) draw up "optional regulations" to implement the Directive, which would not guarantee safety; and

(iii) draw up mandatory regulations to implement the Directive (the preferred option). This will ensure an appropriate level of consumer safety, harmonisation, and ensure the UK meets its treaty obligations to implement this Directive.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The new regulations will be reviewed by the UK, 5 years after coming into force ie in 2015.

<u>Ministerial Sign-off</u> For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

..... Date:

Summary: Analysis & Evidence									
Policy Option: Implement the 2008 DirectiveDescription: Assessment of costs and benefits of the implementation of the Aerosol Dispensers Regulations 2009								mentation	
COSTS	ANNUAL COSTS			Description and scale of key monetised costs by 'main					
	One-off (Transition) Yrs		Yrs	affected groups' Costs to manufacturers have been monetised. We would assume most costs would be passed through to					
	£ 0 - 0.8 r		2	consumers. Any implementation costs will co			l cover chang	ges to	
	Average Annual Cost (excluding one-off)			labelling. However as industry routinely changes labels at least every 2 years and the Directive has a 2 year transistional period, these costs should be minimal.					
CC	£ None			Total Cost (PV) £ 0.8 million					
	Other key non-monetised costs by 'main affected groups' Costs to national authorities have not been included, however the likely costs to the Market Surveillance Authority are likely to be minimal.								
	ANNUAL BENEFITS			Description and scale of key monetised benefits by 'main					
BENEFITS	One-off		Yrs	affected groups' It has not been possible to quantify any of the benefits that will result from the new regulations.				ny of the	
	£ -		2			5			
	Average Annual Benefit (excluding one-off)								
BEN	£-			Total Benefit (PV) £ -					
Other key non-monetised benefits by 'main affected groups' Potential for reduction in production costs for manufacturers. Benefits to industry from reduced legal uncertainty. Harmonising the regulations would potentially help UK exporters. Benefit to the National Health Service by reducing the burden in terms of accident prevention.									
Price Base Time Period Year 2010 Years 10		-	Net Benefit Range (NPV)			NET BENEFIT (NPV Best estimate) £ -0.8 million			
			\sim			2 -0.0 111			
				of the policy/option	?		UK 20 April 2010		
		will the policy					29 April 2010 UK Trading Standards		
	Which organisation(s) will enforce the policy?UK Trading StandardsWhat is the total annual cost of enforcement for these organisations?£ minimal							y Standards	
What is the total annual cost of enforcement for these organisations? 2 minimal Does enforcement comply with Hampton principles? Yes									
Will implementation go beyond minimum EU requirements?							Yes		
What is the value of the proposed offsetting measure per year? £ 0									
What is the value of changes in greenhouse gas emissions?£ 0									
Will the proposal have a significant impact on competition? No									
Annual cost (£-£) per organisation (excluding one-off)					Micro £55k-98k	Small £55k-98k	Medium £55k-98k	Large	
Are any of these organisations exempt? No No N/A								N/A	
	bact on Ad rease of	min Burden £0		line (2005 Prices) ecrease of £0	N	et Impact	(Increase - D £ 0	ecrease)	

Annual costs and benefits: Constant Prices (Net) Present Value Key:

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

OVERVIEW

The Aerosol Dispensers Directive 75/324/EEC (ADD) was introduced nearly 35 years ago to improve the safety of aerosol dispensers. It became out-of-step with new processes and products and was amended last year by Commission Directive 2008/47/EC which adapts the ADD to technical progress.

The new regulations - Aerosol Dispensers Regulations 2009 – will implement the provisions of this new Directive and their primary aim is to protect public health by requiring aerosol dispensers to meet certain safety standards. Industry worked closely with the Commission on the proposal for the new Directive and welcomes the changes within it. The new regulations will:

- Introduce a general obligation for a hazard analysis
- Align flammability criteria with international transport legislation
- Permit alternatives to the Hot Water Bath Test
- Introduce a common maximum filling measure
- Increase maximum filling pressure for metal dispensers

The UK interpreted the ADD as an "optional directive". The UK existing implementation of ADD made the supply of a compliance marked aerosol

(compliance is indicated by the aerosol bearing the reversed epsilon " \Im " marking) which did not comply with ADD an offence, but did not make the marketing of noncomplying aerosols an offence. The option chosen is to implement the ADD so that all aerosols covered by the ADD must comply and be marked accordingly.

BACKGROUND

In 2006 DTI issued a consultation on the provisions in the proposed amendment to the ADD. We consulted over 185 stakeholders consisting of the British Aerosol Manufacturers' Association, individual aerosol manufacturers, small businesses, the chemical industry, the retail sector, consumer organisations, trade associations, charities, enforcement authorities, Government Departments and non-Governmental organizations etc. We received 12 responses, none of which opposed the proposal or indicated any negative impact on their business. Based on further views, received mainly from the UK, the Commission re-drafted its proposal and the amending Directive was published on 8th April 2008. BERR issued a further consultation in April 2009 consulting the same stakeholders on the wording of the implementing regulations. We received nine responses, all of which supported the approach to the transposition of the Directive. The one substantive response requested a transition period and the regulations were amended to incorporate a transitional provision to allow the selling though of aerosols complying with the old regulations in the supply chain until 28th October 2010.

INTERACTION WITH OTHER LEGISLATORY PROVISIONS

- Consumer Protection Act 1987 (the "CPA"): This provides the legal basis for much of the consumer safety legislation introduced in the UK, including the Regulations. Infringement of the Regulations would attract enforcement action under the CPA.
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009) sets out mandatory standards for the safe carriage of aerosol dispensers, amongst other goods. The implementation of the 2009 Aerosol Regulations will update the ADD safety tests and bring them into line with transport requirements.

SCALE AND SCOPE

The value of the UK aerosol industry is around £3 billion with more than 50% of UK production being exported, mainly to the EU. In 2007 the UK filled over 1.25 billion aerosol dispensers. Aerosol dispensers are used in many sectors with cosmetics (perfumes, deodorants, shaving products, hair care etc) being the largest at 68% of all aerosols produced. Next are household products (air fresheners, polishes and window cleaners etc) at 17%, followed by pharmaceutical 8% and automotive/industrial 4%.

Europe is the largest producer of aerosols – over 5.4 billion produced in 2007, so the UK clearly has a large market share.

UK's POSITION

The UK supported the 2008 amending Directive and supports the implementation of these regulations to ensure an updated level of safety of aerosol dispensers.

The UK proposes that compliance with the requirements of the Directive regulations apply to all aerosols covered by the ADD.

RATIONALE FOR GOVERNMENT INTERVENTION

Aerosol safety standards have become out-of-date and do not reflect current processes and products. The new regulations will provide an updated safety framework for aerosols dispensers and provide enhanced consumer protection.

The UK is under a Treaty obligation to implement the 2008 Directive.

We have chosen to implement by applying the requirement to mark and hence comply with the regulations to all aerosols covered by the ADD. Although currently the UK does not require compliance marking for all aerosols covered by the ADD, in practice all aerosols have to meet its safety requirements as they have to comply with the mandatory CDG (Carriage of Dangerous Goods Regulations 2007) which require exactly the same safety testing procedures.

Having a clear mandatory compliance position in the UK regulations will prevent confusion and will help to ensure consumer safety by making sure that <u>all</u> aerosol products are regulated and treated equally. It will also put aerosols safety on the same mandatory footing as all other consumer products safety regulations.

DETAILED PROPOSALS

The new Regulations will implement several changes to aerosol safety requirements:

(a) Obligation to perform a hazard analysis

All aerosol dispensers, irrespective of their design, are within the scope of the ADD but the innovatively designed aerosols of recent years can present hazards which are not currently properly covered. This general obligation to perform a hazard analysis should ensure that all aerosol dispensers marketed now, and in the future, are safe for use by the consumer and that the standards of safety for traditional and for innovative aerosols (such as cooking oil dispensers) are the same.

(b) Flammability

The current ADD requires that aerosols with flammable contents be labelled accordingly but deals only with the flammability of the individual constituents of the aerosol and not with the flammability of the final aerosol product. The regulations will ensure that labelling of aerosols reflects the actual flammability of the contents, under foreseeable conditions of use, and adopts up-to-date flammability criteria based on the UN Recommendations on the Transport of Dangerous Goods. Some manufacturers may have to relabel their products accordingly.

(c) Alternatives to the Hot Water Bath Test

New provisions will facilitate the use of alternatives to the so-called hot water bath test (hWBT) which tests the leak-tightness and burst resistance of filled aerosols at the end of the production line. The hWBT cannot be used to test aerosols containing heat sensitive products (eg food products such as whipped cream etc) because of the elevated temperatures (50° C) used.

Approval to use alternatives had previously to be given by a Committee consisting of the Commission and 27 Member States representatives. This proved bureaucratic, timely and burdensome for industry, Member States and the Commission. Approval will now be transferred to the national Competent Authority who already approves alternative tests under the transport regulations. The Competent Authority for GB is the Department of Transport and in Northern Ireland it is the Health and Safety Executive Northern Ireland.

The changes will allow a greater variety of products – including heat sensitive ones – to be marketed in aerosols and could reduce energy costs on high-speed filling lines.

(d) Maximum filling level

The changes will introduce a common maximum filling of 90% for all types of aerosol. The maximum filling permissible for certain types of metal aerosol will be reduced to 90% from the current maximum permissible level of 95%. This will more effectively guarantee the safety of the consumer from the potential risk of aerosols bursting or leaking when exposed to heat under normal conditions of use.

(e) Maximum filling pressure

The changes will increase the maximum permissible filling pressure to 13.2 bar for metal aerosol dispensers using non-flammable propellants. This will encourage the use of environmentally friendly compressed gases as propellants, resulting in the more efficient usage of aerosol contents while maintaining consumer safety.

MONITORING AND EVALUATION

The new regulations will be reviewed by the UK, 5 years after coming into force ie in 2015.

IDENTIFICATION OF OPTIONS

There are three main options under consideration in this Impact Assessment:

- Option (i) Do nothing
- Option (ii) Draw up "optional" regulations, not requiring compliance with the Directive in all cases covered
- Option (iii) Draw up mandatory regulations to implement the Directive (preferred option)

<u> Option (i) – Do nothing</u>

The first option to consider is to do nothing, which would mean that the UK would not transpose the amended Directive and therefore would not comply with its EU obligations and be at risk of infraction. To do nothing would also mean that consumers are at risk from out-of-date safety standards for aerosol dispensers.

<u>Option (ii) – Draw up "optional" regulations, not requiring compliance with</u> <u>the Directive in all cases covered</u>

Under this option some of the problems with the current legislation could be addressed, but it would lead to a lack of harmonisation as we believe all other Member States will implement the Directive on the basis that all aerosols covered by the ADD must be marked and therefore comply. In addition individual manufacturers may not apply any of the provisions leaving the consumer at risk from the failure of aerosol dispensers not tested to internationally based standards. Therefore, this option does not address the aim of reducing the risk to consumers.

Option (iii) – Draw up mandatory regulations to implement the Directive

This is the preferred option. Implementation of the Directive will update existing aerosol safety legislation.

Our preferred option is to implement by applying the requirement to mark and hence comply with the regulations to all aerosols covered by the ADD. Having a clear mandatory compliance position in the UK regulations will prevent confusion and will help to ensure consumer safety by making sure that <u>all</u> aerosol products are regulated and treated equally. This should not pose an additional burden to industry as the same requirements for safety testing are already mandatory under the transport regulations – which can lead to confusion for manufacturers, retailers and enforcement agencies.

The implementing regulations will be focussed on consumer safety. All other consumer safety regulations in the UK are mandatory and the aerosol dispensers provisions should not be treated differently from other measures to protect the consumer.

The UK is one of only two Member States where national law implements the provisions of the ADD by not addressing the marketing of non-complying aerosols. This will reduce legal uncertainty for manufacturers and enforcement agencies and improve harmonisation of aerosol safety standards with the Community. UK-based manufacturers choosing not to comply would not be as competitively placed as others in UK and within the Community who do implement the regulation.

Benefits

<u>Economic</u>: probably the most significant benefit for manufacturers is the ability to choose a cold water final test method for aerosols rather than a hot water test. The objective is to allow a greater variety of contents to be marketed in aerosols and to render production lines more efficient whilst maintaining high safety standards. This change has the potential to reduce the manufacturing costs for aerosols. We have not been able to obtain any estimates as to the size of these benefits

Notifying an alternative to a hot water bath test will become less bureaucratic and burdensome for industry who will now have to apply only to the UK Competent Authority (Department for Transport in GB or the Health and Safety Executive in Northern Ireland) rather than wait for approval from a committee of the Commission and all Member States.

This option will also support innovation as it harmonises the internal market for aerosol dispensers regardless of their design. It will not create additional burdens for responsible manufacturers but will clarify a legal uncertainty, which may distort competitiveness and will create a common level playing field for all manufacturers and types of aerosol dispensers.

The new regulations will mean transparent state-of-the-art rules for manufacturers. The adoption of UN based flammability criteria will lead to a more realistic appreciation of the related hazards. It will reduce the labelling burden on some manufacturers who will no longer have to label their product as flammable because it contains only a small, diluted quantity of a flammable substance. It will also bring the flammability criteria into line with that required under transport legislation.

<u>Environmental</u>: change to the maximum filling pressure will encourage the use of safer, more environmentally friendly compressed gasses, such as nitrogen or air, by enabling industry to more fully utilise the potential of such propellants.

<u>Social</u>: the main social benefits of the regulation would be to consumers in the form of improved safety of aerosol dispensers and a reduced cost in treating injuries arising from failure of aerosol dispensers. It has not been possible to quantify the number of aerosol injuries. The Home and Leisure Accident

Surveillance Statistics (HASS/LASS) recorded 1900 accidents in the UK in 2002 (the last year for which data is available) which were related to aerosols. Some of these may arise from abuse or misuse of aerosols (which would not be prevented by the new regulations) and some from a failure of the aerosol dispenser itself, which may not have occurred once the new regulations are in force. From the data available it not possible to estimate the numbers of injuries which may be prevented by the new regulations.

Costs

As indicated above, the old regulations have labelling requirements for aerosol dispensers with "flammable contents", but not for the flammability hazard of the final aerosol product, which typically contains a mixture of several substances. The objective of the new regulations on flammability is to ensure labelling of aerosols correctly reflects the actual flammability of the contents under foreseeable conditions of use. We have been informed by industry that a small number of products, estimated to be less than 2.5%, about 500 product labels, may need reclassification and therefore re-labelling for flammability and for addition of the compliance mark.

Taking into account all associated costs (administrative, studio time, approval processes etc), costs to industry could be in the region of \pm 5000 per product design, equating to a maximum total cost of about \pm 2.5m. The direct cost of changing the print without administrative costs etc will be between \pm 100 and \pm 300 per design change. However, we have been informed by industry that label changes are a matter of course. If the changes are made in the normal course of events (they usually change at least every 24 months) then the additional cost is nearer zero. It is worth noting that the new Directive gives industry a 24-month transitional period to run down existing stock. Therefore, based on the information provided by industry, the proposed changes with regard to flammability labelling are likely to have little impact on industry. In the absence of more detailed information the cost has been taken as one third of the maximum potential compliance cost of \pm 2.5m. ie \pm 0.8m. which we believe will be spread over 2 years.

COMPETITION ASSESSMENT

The Directive will apply to all Member States of the EU and is unlikely to have the effect of distorting or removing competition in the market.

SMALL FIRMS IMPACT TEST

The aerosol industry is dominated by around a dozen large producers. Of the remaining 60 or so companies, nearly all are SMEs.

SME trade associations and small businesses were consulted during the public consultation by the Commission in September 2005 and by DTI in it's consultation of 2006. Those consulted included the British Aerosol Manufacturers' Association (BAMA) and individual aerosol manufacturers, including SMEs. Of the 12 responses received, only one indicated any opposition to the proposed changes or foresaw any additional costs to their businesses arising from them.

IMPACT ON THE PUBLIC SECTOR- ENFORCEMENT AND SANCTIONS

These Regulations would be enforced by local authorities' trading standards departments. It is the responsibility of the manufacturers of aerosol dispensers made in the EU to ensure that products comply with the Regulations. Trading Standards are already enforcing the 1977 regulations and will also enforce these updated requirements. There are no reasons to believe this revision of the Regulations will have any substantial impact on them.

HEALTH IMPACT ASSESSMENT

The proposed Regulations will benefit consumers. The updated safety standards will have benefits through reductions in the number of aerosol dispensers injuries.

GENDER EQUALITY IMPACT TEST

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of their gender. In that context and in terms of costs, it has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on a particular gender. In particular, the duty under section 76A of the Sex Discrimination Act 1975 has been considered and does not give rise to any issues.

DISABILITY EQUALITY IMPACT TEST

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of any disability. In that context and in terms of costs, it has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on those with disabilities. In particular, the duty under section 49A of the Disability Discrimination Act 1995 has been considered and does not give rise to any issues.

RACE EQUALITY IMPACT TEST

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of their ethnicity. In that context and in terms of costs, it has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on a particular ethnicity. In particular, the duty under section 71 of the Race Relations Act 1976 has been considered and does not give rise to any issues.

ENVIRONMENTAL IMPACT TEST

The new Regulations will encourage the use of safer, environmentally friendly compressed gasses such as nitrogen or air, by enabling the industry to more fully utilise the potential of such propellants.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	No	No
Rural Proofing	No	No

Annexes