Impact Analysis of Regulating Lead in Consumer Products

Summary

The Norwegian Government has established national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view of eliminating them by 2020, (Prop. 1 S (2009-2010) from the Norwegian Ministry of the Environment, Proposition to the Parliament (Storting) for the 2010 budget year. The substances included in the target are given in the Governments list of priority hazardous substances (the Priority List). Lead is one of the substances in this list.

Lead bioaccumulates and is persistent in the environment. It is toxic in low concentrations, acutely toxic for humans, and chronic lead poisoning may produce neurotoxic and immunological effects. Lead compounds cause damage to the reproductive system. Lead is very toxic to aquatic organisms and can cause long-term undesirable effects in the aquatic environment. Lead bioaccumulates in fish and mammals. This means that the effects must be deemed irreversible. The health and environmental impacts from lead may take many years to show.

In order to limit the risk of lead emissions and the consequences they may have, it is considered necessary to regulate lead in consumer products. It is proposed individual cut off values for the different product groups included in the regulation. Examples of known usages for lead subject to regulation would be building materials, fishing gear, weights, jewellery/costume jewellery, paint/varnish, glue, glaze, enamel, plastic products including building articles such as sections for doors and windows, wallpaper, floor coverings, toys, travel articles, leisure articles, hobby products and textiles.

Lead occurs in consumer products, both in its metal form and as a chemical lead compound. Norwegian sales figures show that the regulation would cover annual sales of a minimum of 450 tons of lead in consumer products. The actual quantity of lead, however, is higher since imported, solid processed articles—especially consumer products—are not included in the sales figures. The Norwegian Climate and Pollution Agency (Klif) has performed analyses of imported products that show that many different products contain large quantities of both lead and lead compounds.

Since lead in products is not converted over the course of a product’s lifetime, the entire quantity of lead used in products may leak out into the environment when the product ends up as waste. Lead runoff may result in pollution of ground water and watercourses. When lead is dispersed into the ground water and watercourses, discharges can result in major damage locally (by, for example, impairing the quality of drinking water) and they may also be introduced to the food chains.

Lead is dispersed in nature through diffuse emissions that are difficult to control. Norway has data from measurements from unprocessed leachate from waste disposal sites that show elevated levels of lead. This confirms that lead in products can leak into nature. The consumer products addressed in the proposed regulation will have the potential of winding up uncontrolled in nature and cannot therefore be handled appropriately as waste. In order to reduce emissions of lead into nature, it is important to remove lead from potential sources, which means that we need to take consumer products containing lead off the market.

For metallic lead, there are several alternatives that both conform to certain technical properties—for example, iron, steel, and copper—and which have less severe health and environmental properties. For many of the relevant PVC products where lead is used as a

stabiliser, there are also alternative substances. Norwegian industry has already entered these into use. There are also replacement substances for lead in paints and glazes.

The proposed regulation may result in some increased costs, but it will result in a significant reduction in the lead introduced into the environment, and reduce the risk of health and environmental damages. The benefits are therefore expected to outweigh the costs on the basis of the anticipated positive effects the proposal will have for health and the environment. The proposal grants exemptions for usages where no alternatives exist or where such alternatives would result in significant costs.

1 Background and Previous Process

1.1 Background

Lead and lead compounds (hereinafter “lead”) covered by the proposed regulation are included in the list of prioritised substances and are therefore among some of the most dangerous substances known to us. The effects of these types of substances are very serious as they are persistent; they bioaccumulate and/or are toxic; they cause harm to the reproductive system and they are carcinogenic. This means that the effects must be deemed irreversible. Prioritised hazardous substances are a serious threat to the health of future generations, to the environment and future food safety. These substances accumulate in nature and in the food we eat and possess properties that make it too late to take measures once the damage is done.

The Norwegian Government has established national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view of eliminating them by 2020, (Prop. 1 S (2009-2010) from the Norwegian Ministry of the Environment, Proposition to the Parliament (Storting) for the 2010 budget year. The substances included in the target are given in the Governments list of priority hazardous substances (the Priority List). Lead is one of the substances in

The efforts to reach these targets are based on the implementation of measures to address identified threats from chemicals hazardous to health and the environment even if the scientific data may not yet be fully documented. Regulation to reduce or eliminate use and release of chemicals hazardous to health and the environment is based on existing knowledge about the health and environmental properties of chemicals and the effects these may have in the short and long terms. This knowledge must be seen in the context of society’s needs to protect health and the environment. The precautionary principle entails that, once a specific threat against health and the environment from chemicals has been identified, initiatives must be implemented to reduce or eliminate the threat even if the knowledge is uncertain.

Products are an important source of lead emissions in Norway. Based on documentation about serious health and environmental effects, occurrence data in Norway and the potential risks of long-term effects, we believe there is a basis for establishing additional regulations that limit the sources and reduce lead emissions.

Consumer products are particularly important since consumers lack the requisite knowledge about the health-related and environmental problems associated with their use and the waste disposal of prioritised hazardous substances. Consumers also do not have the requisite knowledge and opportunity to be able to protect themselves against emissions. The entire population, including vulnerable groups such as children, is therefore exposed to exposure from emissions from consumer products, either directly or indirectly via the environment.

Reducing the quantity of substances hazardous to health and the environment in products is an important step in reducing the quantity of hazardous waste that is generated. Consumer products are an important source of uncontrolled dispersion of hazardous substances into the environment.

The increased dispersion of substances released from products and then spread into the environment results in human exposure by breathing, eating, drinking or by absorbing the substances through the skin. Dispersion of persistent substances stored in living organisms constitutes a special problem because they take a very long time to be reduced to a level that does not involve risk of damage. Additionally, there is exposure to various different substances, and our knowledge about synergistic effects—i.e. how humans and the environment are affected by exposure to several substances at the same time—is incomplete.

The most effective manner in which to limit problems associated with a substance present in a number of different products is to regulate it as close to the source as possible and as early in the supply chain as possible. It is much more difficult to take steps to prevent uncontrolled dispersion of hazardous substances at a later point in time after the products have already been put on the market. The proposal to regulate lead in consumer products therefore fulfils the general principles of risk management.

The health and environmental effects from lead can take many years to show. It is therefore crucial that the risk associated with the use of products containing lead should be limited, especially because monitoring data show that the substances are retrieved in the Norwegian environment. In order to limit the risk, we believe it is necessary to regulate consumer products that contain lead in the homogenous individual parts of products. We propose regulation using various limit values depending of what is regulated. Products containing less than these limit values may be sold legally.

1.2 Previous Process

Proposals for regulating lead in consumer products were included in a previous proposal to regulate a number of prioritised hazardous substances in consumer products, which Norway submitted for national consultation and notified to the ESA (pursuant to Directive 98/34/EC) and the WTO in 2007. A limit value of 0.01 weight % was proposed for lead and lead compounds in consumer products with certain exceptions. We received several comments on the notified proposal, mainly from trade organisations for electronics, metals and glass. Most comments pertained to the perceived excessive stringency of the proposed limit value for several usages, and it was discussed that the Norwegian proposal should be harmonised with the ban on lead that exists in Denmark. The EU Commission pointed out that the Norwegian proposal would affect many products and that the emissions from these would be marginal in relation to the remaining lead emissions in Norway.

The proposal that is now being notified is a revised version of the 2007 proposal and is a product of the comments submitted in the consultation process that was carried out at the time.

2 Problem Description

2.1 Substance or Substance Group

This impact assessment covers lead and lead compounds. Lead here refers to lead in its metallic form as well as in chemical compounds. The various lead compounds cover several CAS registry numbers.

2.2 Definitions and Limitations

This impact assessment covers lead and lead compounds used in consumer products. Consumer products in this relation refer to any and all products intended for consumers and which can reasonably be expected to be used by consumers, in line with the definition set out in section 2 a of the Norwegian Act of 11 June 1976 No 79 Relating to Products and Consumer Services Control (Norwegian Product Control Act).
Lead is currently regulated for some applications both in Norway and within the EU. Range of application already regulated in other rules and regulations are not covered by this proposal.

The regulation does not cover food products, food packaging, fertilizer, medical devices and means of transport, permanently mounted equipment for means of transportation and tyres and similar accessories for means of transportation. This range of application will not be described in greater detail in the environmental impact assessment.

2.3 Occurrence

Lead has been detected in humic strata, in sediments in lakes and fjords, soil and in animal species. In several places in Norway, lead concentrations in nature are higher than what are considered natural background values. The elevated levels are caused by matter introduced via air flows from other countries (long-distance transport) and by local emissions. Reducing local emissions is an important part of the effort to meet the national target of eliminating national emissions of chemicals that constitute a serious threat to health and the environment before 2020. In that regard, a significant contribution will be to cease production, import, use and sale of consumer products containing lead.

Lead levels are being measured in rivers, sediments, air and precipitation, blue mussels and fish in a number of programmes. Lead has been detected in sediment samples collected in the inner Oslofjord and across background levels in cod liver and blue mussels.

Lead can be dispersed in nature through diffuse discharges, which are difficult to control. Runoff of chemicals hazardous to health and the environment may result in pollution of ground water and watercourses. When substances hazardous to health and the environment are dispersed into the ground water and watercourses, they can cause major damag locally (for example, by impairing the quality of drinking water) and may also be introduced to the food chains. Runoff of chemicals hazardous to health and the environment may also contaminate the ground below an illegal waste site. From there, they may enter the food chains.

Persons operating disposal sites for waste must be properly authorised to do so under the Norwegian Pollution Control Act. The permit will establish requirements for monitoring and performing annual measurements of discharges of environmental toxin, including lead from

waste disposal sites.[1] The quantity and concentration of lead are measured in the leachate from waste disposal sites. The findings must be reported to the pollution control authorities and registered in Klif's "Pollution" database.

We have data from measurements of unprocessed leachate from waste disposal sites that show elevated levels of lead. This shows that lead in products can leak out into nature. In addition to authorized waste disposal sites, waste is being disposed of in nature and stored at various storage sites, so-called "rogue fills." Even though efforts surveying and controlling these have been intensified, there is still waste that is stored improperly in several locations.

Results from these measurements in 2007–2008 show that the amounts of lead discharged from about 80 waste disposal sites in Norway vary relatively greatly, but for a large number of them there were significant quantities of lead being discharged into the leachate every year. There are no total numbers for discharges of lead from these waste disposal sites. The quantities from the various waste disposal sites vary from a few grams to several kilograms of lead annually. The concentration of lead in the leachate varies to a lesser degree and constitutes significant quantities for a large number of the waste disposal sites. If the measurement findings are compared with the mandated lead concentrations in the table for state classification categories for heavy metals in fresh water (Table 1), it turns out that 80 to 90% of the plants report concentrations of lead in unprocessed leachate corresponding to State Classification Category IV or V, i.e. heavy or very heavy contamination.

Table 1: Excerpts from Guideline for Classification of Priority Substances in Freshwater, Table 6)[2]

	I Insignificant Contamination	II Moderate Contamination	III Marked Contamination	IV Heavy Contamination	V Very Heavy Contamination
Lead µ/l	< 0.5	0.5 – 1.2	1.2 – 2.5	2.5 – 5	> 5

For about 25% of the 80 waste disposal sites submitting reports of discharges, the leachate is routed to municipal processing plants. In 2008 discharges of lead from municipal processing plants were registered at 1,200 kg (ref. Statistics Norway). For about 75% of the waste disposal sites, the recipients of leachate were streams, rivers and fjords. Which amounts of lead might end up in recipients depends on whether or not the waste disposal sites have their own processing plants and how good they are.

The potential thus exists for accidental discharges of lead from several places, especially through diffuse discharges that are difficult to control. This is in spite of the fact that waste must be disposed of at authorised waste disposal sites and have leachate collection facilities for processing. It is therefore not improbable that significant quantities of lead might be introduced to nature and do damage to the environment and health either directly or indirectly.

2.4 Health and Environmental Impact – Risk Assessment

Health and environmental damages related to lead exposure have been known for a great many years and are well documented.[3] Uptake of lead often takes place slowly and under long-term chronic exposure. Secretion of lead from organisms occurs slowly. The biological half-life of lead in humans, mammals and fish is very long.

[1] Chapter 9, Norwegian Regulation on the Recovery and Treatment of Waste, Guideline TA No 2077/2005.
[2] TA No 1478/1998, Classification of Environmental Quality in Freshwater.
[3] UNEP Interim Review of Scientific Information on Lead and Cadmium, October 2006.

Health

Lead bioaccumulates and does not degrade. It is toxic in low concentrations, acutely toxic for humans; moreover, chronic lead poisoning may produce neurotoxic and immunological effects. Lead compounds are harmful to the reproductive system (classified as Rep. Cat. 1), may produce brain damage, congenital malformations, damage the capacity to reproduce, may also result in premature births, stillbirth or low birth weight and may inhibit blood formation in humans. In lead compounds, for example, lead acetate is classified as a potential carcinogen (Carc. Cat. 3).

Humans are exposed to lead primarily by inhalation but also through the gastrointestinal system. Organic lead is also taken up through the skin. The blood transports the lead to cells and tissue in the body. Most of it is stored in the skeleton. Lead accumulates in the skeleton and soft tissue and is slowly excreted. The half-life for lead in the skeleton is about two years.

Lead uptake in the body can, among other things, be significant to a child's ability to learn, its behaviour and intelligence. Health effects in humans have been shown at blood lead values from 0.3 µmol/l. At that value, effects on the metabolism, kidneys and the cardiovascular system become apparent. These effects are based on a great number of epidemiological studies and do not constitute a serious health risk for the individual human being. In studies of children, at blood lead values of about 0.5 µmol/l, there have been findings of delayed development, reduced IQ and behavioural disorders. Other registered effects are anaemia and reduced hearing. At blood lead levels of about 1.5 µmol/l, several serious health effects begin occurring in adults. The differential between the blood lead content measured in women of child-bearing age and children without known lead exposure, and the levels where measurable effects have been found at group level is relatively small (factor 2-5). A foetus may experience brain damage at blood lead levels that are harmless to the mother. Lead passes via the placenta to the blood of the foetus, and it is also excreted into breast milk. Damage to the central nervous system in small children has been shown at blood lead levels of down to 0.5 µmol per litre blood.

Sources of lead exposure can include polluted air, drinking water and foods or by inhaling dust or by ingesting soil. Even small amounts of lead may result in health damage. Identified risk groups are, among others, women of child-bearing age, foetuses, children who swallow or suck on lead-containing products, sport fishermen who cast their own fishing equipment using lead, persons using solder for hobby purposes, and persons exposed to lead through the incorrect use of enamelled products such as ceramics purchased abroad.

Lead in products such as crayons and jewellery may constitute a serious health risk in that children may swallow such products. Children who swallow small parts containing lead may be exposed to high lead concentrations since lead ions are released from the metal in the stomach's acidic environment. Fatalities have been reported in the United States where children have swallowed parts of jewellery containing lead.[4]

Environment

Lead is very toxic to aquatic organisms and may cause long-term undesirable effects in the aquatic environment (classified as R 50-53). Lead bioaccumulates in fish and mammals.

Lead ions are released from metallic lead, especially in an acidic environment. When metallic lead is converted to compounds that are bioaccessible and toxic, it impacts health and the

[4] RAPEX 2006, Week 12, 0191/06.

environment negatively. This conversion occurs via acids in the stomach in various species and via corrosion in the ground and water. Variations in corrosion speed depend heavily on the conditions to which metallic lead is exposed. Humidity and pH factor are of decisive significance to corrosion speed. Lead compounds are bonded strongly to particles in soil, and mobility is usually low but increases with increased acidity levels. In water, lead may occur as lead ions in acidic water (with high mobility and bioavailability), or as lead carbonate in more alkaline water, as complex with dissolved organic material absorbed to particles such as clay and organic material (with lower mobility and limited bioavailability).

When lead ends up as waste, it is dispersed into the environment. Products containing lead, which end up as waste, may through combustion contribute to deposition of lead from the air. Lead may also leak out from lead-containing products that end up in waste deposit sites. Lead in the environment may result in the direct poisoning of birds and other animals that ingest lead (e.g. from fishing equipment), directly or indirectly via the food chain.[5]

Metallic lead is a smaller contamination problem than lead compounds. The reason for this is that several of the usages for metallic lead, for example, batteries and accumulators containing lead, have satisfactory collection and waste processing schemes. Emissions related to the use of these products are minimal.

However, the use of metallic lead that does constitute a problem is linked to products that are difficult to collect after use. This typically applies to consumer products such as fishing equipment, jewellery/costume jewellery, hobby products and drapery and curtain weights. These products often end up in nature (fishing equipment) and in regular household waste. As household waste lead may leak from the products and remain in the leachate before it reaches the recipients.

Chemical lead compounds in plastic and paint can be dispersed through recovery/recycling of the materials, and thereby be recycled in use before they finally end up as waste.

3 Range of Application and Alternatives

3.1 Known Range of Application

Lead can occur in products such as pure metal in, for example, ammunition, boat keels, weights, fishing equipment, jewellery and costume jewellery, hobby products. Lead can also occur in the form of chemical lead compounds as stabilisers in plastic,, and as colour pigments in paint and glazes. Lead can also occur as such in many products made of plastic, painted or enamelled products, or in glassware, crayons, toys, electrical and electronic products and batteries/accumulators. Lead may occur in imported products, especially in products made out of PVC plastic and products made out of recycled PVC-plastic, especially from countries outside Norway and the EU. Usage of lead as a stabiliser in PVC plastic has been reduced by the Norwegian industry.

Examples of known applications covered by the proposed regulation include building materials, fishing gear, weights, jewellery/costume jewellery, paint/varnish, glue, glazing, enamel, plastic products including building articles such as sections for doors and windows, wallpaper, floor coverings, toys, travel articles, leisure articles, hobby products and textiles.

[5] COWI, Final Report November 2004: Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers and candlewicks.

3.2 Sale and Emission of Lead in Norway

Based on sales numbers for lead in products registered in Norwegian discharge and emissions statistics, the amount of lead in product types covered by the proposed regulation, in full or in part, is about 9,000 tonnes annually (in products both for commercial and private use). We do not have detailed knowledge about how great a share of this constitutes lead in consumer products, but a conservative estimate is about 5%, which amounts to about 450 tonnes of lead annually.

Figures for sales and discharge/emission of lead in 2008 are listed in Table 2 below.

We have limited information about the content of lead and lead compounds in imported products and therefore have a very limited overview of the quantity of imported products that may contain lead and the amount of lead they may contain. Lead compounds in imported solidly processed products are not registered in the Norwegian product register, and a large part of these products and emissions from these are therefore not included in the registered figures.

The vast majority of products containing lead will have no lead emission of significance during their useful lives. The products have long useful lives and will not end up as waste until several years after the time of sale.

Lead headed for recovery might end up in new consumer products and, in this manner, re-enter the waste chain, risking that they will not be properly handled once they end up as waste.

PVC containing lead may also go to recovery. Recycled material containing lead can then be mixed with new PVC, which means that lead can be distributed in major quantities in new PVC products. In connection with chemical recovery of materials, lead can be released and end up in a waste fraction and thereby be emitted into the environment via air or water.

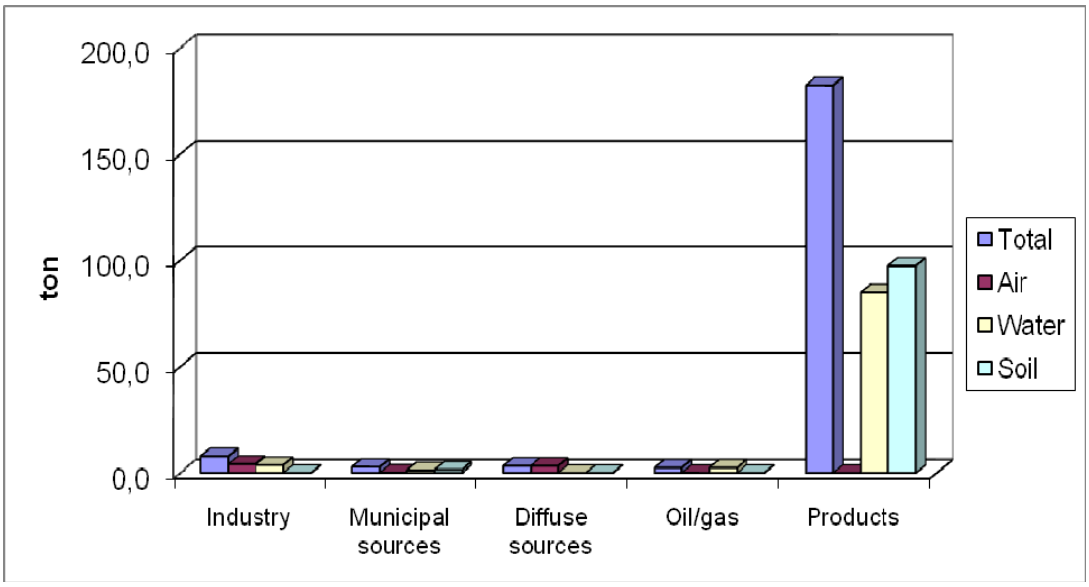
Other products containing lead end up as ordinary waste, which are either collected in the municipal waste management system (for incineration or at a waste disposal site) or dumped as waste in nature (rogue fills).

The figures available for sale and emission of lead into air, water and soil in 2008[6] was estimated at about 180 tonnes. These are emissions from industrial activities (reported measurement findings) and from some product groups (calculated discharge quantities). The emission quantities of lead in 2008 are dominated by emissions from products and constitute about 92% of total emissions in Norway (approx. 162 tonnes), see Fig. 1. Discharges from contaminated land of about 10 tonnes are not included.

Discharges into water are dominated by discharges from fishing equipment, while discharges into soil are dominated by discharges from ammunition. It is assumed that discharges into water from fishing gear for consumers amount to about 43 tonnes (which is the same as discharges from fishing gear for commercial use), registered discharges of lead into municipal drainage and sewage sludge total about three tonnes in 2008.

[6] "Prioriterte miljøgifter – Status i 2008 og utslippsprognoser" [Prioritised Hazardous Substances – Status in 2008 and Discharge Prognoses].

Figure 1: National emissions of lead into air, water and soil as well as total emission of lead in Norway (2008) distributed across sources.



Increased import of products, especially PVC products from countries without regulations in the area, will (relatively speaking) constitute a more important source of lead discharges in the Norwegian market as we gradually gain control over more of today's most significant sources, such as discharges from industry and product groups collected and processed properly. Consumer products are an important source of uncontrolled dispersion of prioritised hazardous substances into the environment.

Table 2: Sale and Emissions of Lead in Norway 2008

Sources	Sale (tonnes)	Emissions into air, soil, water (tonnes)	Waste (tonnes)
Industrial sources		6	
Municipal sources		3	
Diffuse sources		3	
Oil and gas activities		2	
Products		162	
Lead shots and other ammunition	105	76	11
Paint and varnish*	13	1	Not known
Laboratory chemicals	0.05	0	0.03
Plastic (additive in PVC)*	3	Not during useful life	Not known
Glassware*	77	Not during useful life	Not known
Blasting sand	3	1	1.5
Batteries, accumulators	13,566	Not during useful life	12,941
Metallic products (industry and building materials)*	8402	Not during useful life	Not known
Cables	7322	Not during useful life	Not known
Fishing gear*	338	85	169
Boat keels	2,226	Not during useful life	Not known
Glazing*	5	Not during useful life	Not known
Other metallic products*	226	Not during useful life	Not known
Other products*	12	Not known	2.6
Total	***32,297***	177	Not known

* Covers consumer products, in full or in part, which are proposed to be regulated in new regulation.
The sales figures for the various product groups were gathered from several sources:

- Lead shots and other ammunition: Statistics for foreign trade, the Norwegian Defence Forces, The Voluntary Sharpshooters Association, and the Norwegian Shooting Association.
- Paint and varnish*: Product Register.
- Laboratory chemicals: Product Register.
- Glassware*: Product Register, Statistics for foreign trade.
- Blasting sand: Producer/supplier.
- Batteries, accumulators: Statistics for foreign trade, Norwegian Automobile Importers' Association.
- Metallic products*: Statistics for foreign trade.
- Cables: Cable manufacturers.
- Fishing gear*: Producer, importer.
- Sail boat keels: Statistics for foreign trade.
- Glazing*: Product Register.
- Other metallic products (misc. minor products)*: Statistics for foreign trade.
- Other products (misc. chemicals)*: Product Register.

Analyses conducted by the Norwegian Climate and Pollution Agency (Klif) during the period 2005–2009 show discoveries of lead in various imported plastic products, among other things, plastic-coated textiles, other plastic products and jewellery (see Table 3).

The products analysed were imported and primarily produced in China. They are not registered as products containing lead in public statistics for foreign trade. These products have therefore not been included in the national overview of sales (Table 2), and emissions and discharges have therefore also not been calculated and included in the overview of transnational emissions and discharges of lead.

In Table 3, only products have been included that contains more than 0.1 percent lead by weight (1,000 mg/kg).

Lead has also been discovered in many other products in the range of 0.01-0.1 percent by weight.

Table 3: Quantity of lead in consumer products—analysis findings.

Product	**mg/kg** (rounded to nearest 100)	**Percent by weight (%)**	**1.** Metallic lead **2.** Chemical lead compound
Car child seat covers*	3,100	**0.3**	2
Lunch boxes*	1,139	**0.1**	2
Garden hoses*	4,500	**0.5**	2
Spare canisters for petrol*	5,800	**0.6**	2
Backpacks*	2,600	**0.3**	2
Swing set seats*	3,000	**0.3**	2
Toiletry bag*	1,800	**0.2**	2
Rainwear***	15,000	**1.5**	2
Wallets***	12,000	**1.2**	2
Purses*	2,100	**0.2**	2
Purses*	12,400	**1.2**	2
Scooter handle***	8,900	**0.9**	2
Jigsaw puzzle clock*	6,200	**0.6**	2
Jigsaw puzzle with magnets*	40,300	**4.0**	2
Pail – malt*	16,000	**1.6**	2
Ring*	9,500	**1.0**	1
Jewellery with pendant**	800,000	**80**	1
Jewellery with pendant**	840,000-900,000	**84-90**	1
Earrings**	410,000	**41**	1
Earrings**	750,000	**75**	1
Ring**	760,000	**76**	1
Jewellery with pendant**	730,000-940,000	**73-94**	1
Jewellery with pendant**	52,000	**5.2**	1
Armband**	860,000-900,000	**86-90**	1
Jewellery with pendant**	780,000	**78**	1
Jewellery with pendant**	2,000	**0.2**	1
Jewellery with pendant**	30,000-240,000	**3-24**	1
Jewellery with pendant**	820,000-920,000	**82-92**	1
Jewellery with pendant**	790,000	**79**	1
Jewellery with pendant**	800,000-940,000	**80-94**	1
Jewellery with pendant**	30,000-200,000	**3-20**	1
Jewellery with pendant**	840,000-870,000	**84-87**	1

* XRF measurement by the Norwegian Climate and Pollution Agency (Klif).
** Analysed by the Assay Office, Birmingham, Report 19 September 2008, 2008/167.82.
*** Analysed by Force Technology.

3.3 Alternatives to Lead in Products

The quantity of lead in products has been reduced throughout several decades. This shows that there are alternatives in many types of products, and that it is possible to replace lead with other substances. However, we still find lead in many products where lead could have been replaced with other substances less hazardous to health and the environment. This shows a need to continue the work on reducing the quantity of lead in products, and in particular this applies to imported products.

There are several reports that provide overviews of alternatives to lead. In that regard, we might mention that

- UNEP (United Nations Environment Programme) has prepared a report with an overview of scientific information about lead.[7]
- Since 2001, Denmark has had separate regulations regulating the use of lead and lead compounds for selected applications. In connection with amending these regulations in 2006, it was established that there had been a positive trend in finding alternatives to lead and lead compounds both in Denmark and internationally.[8] Their regulatory efforts throughout almost ten years show that there are alternatives to lead across a number of usage areas.
- Sweden has prepared a report on lead in products. This report lists several alternatives.[9]
- Norway has evaluated alternatives to lead in PVC[10] and concluded that there are alternatives to lead in PVC.

The table below shows some potential alternatives to lead and lead compounds in product types covered by the proposed regulation.

Table 4: Alternatives to lead in consumer products.

Product	**Alternatives and limitations**
Metallic lead	
Fittings around windows, pipes etc.	Soft profiles: Zinc, which is soft and can be treated almost like lead. Aluminium combined with polymers or rubber; Rigid profiles: Stainless steel, aluminium or other materials.
Roofing sheets	Several alternatives are available. Difficult to find alternatives for historical buildings.
Fishing gear	Alloys of zinc and iron/steel as well as alternatives based on iron, wolfram, tin and bismuth. Iron/steel are considered the most eco-friendly and most reasonable alternatives. Zinc is less damaging to the environment than lead. For tin, wolfram and bismuth, the data is incomplete with respect to potential environmental damage.
Other: Toys, jewellery, curtain weights, tea candles and other candles, hobby items	Alternatives vary with use and may be plastic, tin, aluminium, stainless steel, iron, precious metals, etc. Candlewicks can be replaced with thicker cotton thread.
Lead compounds	
PVC stabilisers	Alternatives include calcium/zinc compounds.
Pigments	Several alternatives are available, e.g. tin-zinc-titanate, bismuth vanadate. Various substances dependent on cost, colour, weather resistance, etc.
Rust-preventing primers	Zinc phosphate or zinc oxide combined with ferrous oxide.
Drying agents in paint	Several alternatives are available, e.g. zirconium or calcium-based compounds.
Pigments and glazings	Several alternatives are available, e.g. alkali borosilicate, zinc/strontium and bismuth compounds.

[7] UNEP Interim Review of Scientific Information on Lead, October 2006.
[8] Evaluation of the Danish Statutory Order on Lead, Danish Ministry for the Environment—Environmental Protection Agency, Environmental Project No 1080 2006.
[9] Swedish Chemicals Agency, Bly i varor [Lead in Products], Report No 3/07.
[10] Environmental impact assessment of potential regulations for the phasing out of lead in PVC, Norwegian Pollution Control Authority (SFT), TA 1964/2003.

4 Current Policy

4.1 National Goals

Norway has national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view to eliminating them by 2020, (Prop. 1 S (2009-2010)) from the Norwegian Ministry for the Environment. Proposition to the Parliament (Storting) for the 2010 budget year):

- Discharges or emissions of some Priority hazardous substances (*cf.* Priority List) must cease or be reduced significantly before 2010.
- Discharges or emissions and use of chemicals that constitute a serious threat to health and the environment must be reduced continuously with the goal of ceasing emissions and discharges within one generation (i.e. before 2020).

Thirty substances and substance groups have been prioritised and listed on the Priority List, which covers this objective. Lead is one of the substances included in the Priority List.

4.2 Regulation of Lead of Products in Norway

Lead is regulated in several areas by the EU/EEA rules and regulations, which have been implemented in Norwegian law. The key areas for regulation in Norway are listed in the following.

Norwegian Ministry for the Environment (Norwegian Climate and Pollution Agency)

- Electric and electronic products: Limit of 0.1%. Exceptions for certain areas. The RoHS Directive (Directive 2002/95/EC)/section 3-18, Annex V of the Norwegian Regulation on restrictions on the use of chemicals and other products that endanger health and the environment (Product Regulations).
- Paint: Ban on lead carbonates and lead sulphates. Exemptions may be granted for restoration works. Directive 89/677/EEA, Articles 17 and 18/section 2-5 of the Product Regulations.
- Packaging: Total of lead, cadmium, mercury and hexavalent chromium may not exceed 100 mg/kg. Exemptions for packaging exclusively produced of lead crystal glass. Article 11 of Directive 94/62/EC/section 3-11 of the Product Regulations.
- Batteries: Ban on incorporated batteries exceeding 0.4% lead (with the exceptions set out in Annex II of Chap. 3 of the Product Regulations). Directive 91/157/EEA, Directive 93/86/EEA and Directive 98/101/EC. Section 3-14 b, *cf.* 3-13 d, of the Product Regulations. A new battery directive (Directive 2006/66/EC) has been adopted.
- Petrol: Ban on lead levels exceeding 0.005 g/l. Directives 98/70/EC and 2003/17/EC. Section 3-16, Annex IV of the Product Regulations. The limit has been established because lead occurs naturally in crude oil. Lead is not added to petrol in Norway or the EU.
- Lead shots: Ban on lead shots. Section 2-5 of the Product Regulations.

Pursuant to section 7-1 of the Product Regulations, dispensation may be granted on a case-by-case basis from provisions set out in the Regulations.

Norwegian Ministry of Justice and the Police (Directorate for Civil Protection and Emergency Planning)

- Toys: Chapter 4, Annex 9 of the Norwegian Regulations on Toy Safety (Directive 1988/378/EEA and 2008/329/EC).

Norwegian Ministry of Health and Care Services (Norwegian Food Safety Authority)

- Cosmetics: Norwegian Regulations on Cosmetics (Directive 76/768/EC, Annex IIA: Prohibited. Trace amounts permitted. In cosmetics 20 mg/kg. In toothpaste 1 mg/kg.
- Food packaging: Regulation on materials and articles intended to come into contact with food (Food Contact Regulation) (Directive 1935/2004/EC), Annexes III and IV: Limit values for leaking of lead.

Norwegian Ministry of Agriculture (Norwegian Food Safety Authority)

- Discharged sludge: Norwegian Regulation on fertiliser products, etc.: Requirements for contents of heavy metals in fertiliser and soil, where foods are cultivated, requirements for use of sludge. Limit value for lead: 50 mg/kg TS.

Additionally, there are regulations and requirements for lead and lead compounds in rules and regulations for hazardous waste, disposal and incineration of waste, and lead content in drinking water and water deposits.

4.3 Efforts to Regulate Lead Abroad, Regionally and Globally

In addition to EU directives regulating lead and lead compounds in several areas, a few countries also have national regulations relating to lead in products. There are also efforts in several other countries and globally to pursue stricter regulation of lead. The following contains some of the regulatory measures that already exist and others that are in progress.

Denmark

Denmark has separate national regulations relating to lead and lead compounds governing the use of lead across several areas: Danish Executive Order No 1082 on prohibiting the import and sale of products containing lead (as amended in September 2009).

This executive order was notified in accordance with Directive 98/34/EC of the European Parliament and of the Council (Information Procedure Directive), as amended in 98/48/EC of the European Parliament and of the Council. The order contains provisions that implement parts of Council Directive 89/677/EEA (Official Journal L 398/89, p. 19). Comments were submitted by several EU Member States when the proposal was notified. The Danish government, however, concluded that the Danish ban complied with the treaty requirements, and the regulation was entered into force on 1 December 2000.

Denmark justified the need for its strict regulations by stating that their chemical policy should prevent lead from accumulating in the biosphere (which consists of all living organisms on earth, of animal and vegetable origin) or the technosphere (consisting of man-made materials). It was also noted that it was desirable to eliminate lead from the waste stream to ease waste handling and minimise the amount of harmful substances in the waste. They wanted to avoid completely exposing people to lead, because of its harmful effects even in very small quantities. Basically they do not want their population to be exposed to the risk of lead exposure.[11]

[11] Poul Bo Larsen, Danish Environmental Protection Agency: Statement to Jyllandsposten.

The Danish regulation bans the import and sale of products containing lead. Lead here refers to the basic element lead, both in its metallic form and in chemical compounds. Products containing lead or lead compounds here refer to products in which lead is an ingredient with more than 100 ppm (mg/kg) (0.01%) in the product's individual components.

For products containing a chemical lead compound, there are some exemptions listed which apply until further notice, primarily in specialised areas that can be defined as commercial use, electrical and electronic products (EE products), glass for special purposes, glazing for bricks and tiles and means of transportation.

The regulation also prohibits metallic lead in specified products and product groups, such as products for hobby purposes, jewellery, building articles, fishing gear for consumers and curtain weights (lead weights).

For the areas that were regulated, there are good alternatives that can be used instead of lead.

The regulation was revised in 2007. In advance of this revision, an impact assessment was carried out of any potential amendments (Environmental Project No 1080 2006). A special assessment was performed for areas for which exemptions had been granted in the regulation as well as for areas/product groups for which dispensation applications had been received.

The conclusion was that an adjustment could be carried out with increased utility value without major financial impact. For several areas, it turned out that a transition to lead-free products had already occurred. It was proposed that more exemptions relating to chemical lead compounds be removed from the regulation, and to add more areas where metallic lead could be used.

Several provisional exemptions could be cancelled because alternatives had been developed, among other things, for glazes, enamels and pigments for crafts, car windows and coating for flat glass and metallic lead for repairs and rebuilding of houses. The assessment concluded that it was relevant to adjust several items of the regulation. Direct and indirect discharges of lead into the environment through production, use and waste handling of products containing lead could thereby be reduced through further regulation.

A few areas still have no alternatives. However, this particularly applies to areas related to commercial use.

Sweden

The environmental authorities in **Sweden** were tasked by the government to investigate the impact of regulating lead in products.[12] Costs and alternatives were analysed. On the basis of these analyses, the recommendations included the following:

- Regulation of lead in fishing gear.
- Regulation of lead in consumer products, including in tin soldiers/solder for hobby use, jewellery/costume jewellery, crayons for hobby use, candlewicks, weights.

Sweden has had a scheme for the voluntary phasing out of lead fishing gear for private use since the 1990s. The Swedish Chemicals Agency partnered with the sports fishing industry and other relevant players to implement an information campaign in 1998 about lead-free

[12] Swedish Chemicals Agency, Bly i varor [Lead in Products], Report No 3/07.

fishing, but this did not result in a sufficient reduction in the use of lead-free fishing gear among leisure fishermen.

EU

Lead is present in many products and a few lead compounds are regulated in the EU/EEA through various legal instruments, *cf.* item 4.2.

Three lead compounds were on the list of candidates of Substances of Very High Concern (SVHC) in REACH December 2009.

- Lead chromate, CAS. No 7758-97-6
- Lead chromate molybdate sulphate red (C.I. Pigment Red 104), CAS. No 12656-85-8
- Lead sulfochromate yellow (C.I.Pigment Yellow 34), CAS. No 1344-37-2

Lead and organic lead compounds are on the list of prioritised substances in the water framework directive as a B* substance. This means that lead is being considered by the EU for inclusion in Group A substance.[13] Discharges or emissions of A substances must cease before 2020. The water framework directive has been implemented in the Norwegian water regulations.

Other

The Netherlands has been investigating the area for a while and is currently assessing a voluntary scheme to phase out fishing gear containing lead. In the **United States, Canada and the United Kingdom**, there is a ban on the use of fishing gear containing lead in parts of the countries.

The **United States and Canada** prohibit lead in jewellery, and **Japan** is considering introducing similar rules. **Finland, the United States, Canada and Australia** all have implemented rules against lead in candlewicks. In addition **Canada** recently (November 2010) adopted changes to their Hazardous Products Act (HPA), which places a regulatory limit of 90 mg/kg total lead on the following categories of consumer products:

> (1) products, other than kitchen utensils, that are brought into contact with the user's mouth in the course of normal use; and
>
> (2) products intended for use in play or learning by children under the age of three years

The environmental authorities in **France** have drawn up a report on lead in consumer products and concluded that lead in consumer products must be limited.[14] On the basis of this, they have prepared a restriction proposal to limit lead in jewellery.[15] The proposal has been submitted to the European Chemicals Agency (ECHA) and will be considered further in the EU system. It has been sent out for public consultation with a response deadline of 21 December 2010.

International Conventions on Lead:

Lead has been prioritised in the North Sea Declarations and is covered by the protocol for heavy metals under the UNECE Convention on Long-range Transboundary Air Pollution. The UNECE Protocol covers both requirements for reductions in emissions and use of the best

[13] Regulations relating to a framework for water management (Water Regulations), Annex VIII (EU Water Framework Directive).

[14] Advantage of limiting the use of lead in a number of consumer products, ISBN-NET: 978-2-11-097006-0

[15] http://echa.europa.eu/consultations/restrictions/information_note_lead_in_jewellery_en.asp

available technology (BAT). Lead and organic lead compounds are on OSPAR's List for Priority Action (2007). Under OSPAR, the environmental protection ministers of the participating countries have given their signatures that, among other things, within one generation (25 years), lead must only be present in the environment in concentrations corresponding to its natural occurrence.

Within the International Forum for Chemical Security (IFCS) and the UN's environmental programme (UNEP), it is currently being studied to determine if there is a basis for more international agreements to limit the use of lead.

5 Proposal for Regulation and Reasons

Based on the documentation we have about serious health and environmental effects, occurrence data in Norway and the potential risk of long-term effect, we believe there is a basis for establishing additional regulations that limit the sources and reduce the emissions of lead. The products covered by the proposal total a minimum of about 450 tonnes of lead. This is a potential source of discharge/emission of lead into the environment, and it is a significant quantity of a substance that is undesirable, and for which goals have been established for its phasing out before 2020. Lead is leaking from waste disposal sites, and measurements have shown the presence of lead in leachate, which is routed to various recipients. We do not have an overview of the quantities captured by processing plants and how much ends up in the environment.

The key objection to the proposal that was sent out for public consultation in 2007 from most bodies consulted was that the limit value was too stringent, and that the proposal was too comprehensive in that (among other things) it covered the presence of lead in metals and alloys.

We have studied Denmark's revised regulation of lead in greater detail, and we have now revised our proposal to bring it in line with the Danish regulation. Norway's proposal exclusively covers regulation of lead in consumer products, while Denmark's regulation also covers products for commercial use.

We have taken into account several of the comments submitted during the consultation process in 2007 in establishing a proposed limit value and the scope of the regulation. This means that the Norwegian proposal will regulate consumer products containing more than 0.01 weight % lead and distinguishes between metallic lead and chemical lead compounds. The scope of the regulation will be different for these two usages. There are alternatives to the use areas for which regulation is proposed, and we have exempted several use areas where there are currently no sufficiently acceptable alternatives.

The proposal does not cover use areas such as steel, tin, brass, aluminium alloys, copper and special glass. We were made aware via the consultation process that products utilising recycled glass as raw material would not be able to meet the limit value of 0.01 weight % lead. It is an objective to increase recovery of glass, and it is important to facilitate such recovery where expedient and possible. We are therefore proposing a special limit of 0.05 weight % lead for products made out of recycled glass. The areas are otherwise regulated by the RoHS Directive (Directive 2002/95/EC) where the limit is 0.1 weight % lead in the products' homogenous parts, are exempted from the proposal to regulate lead in consumer products. Other exemptions include areas in which lead is already regulated in Norway (see Chap. 4.2).

Expanded regulation will reduce the amount of lead as a potential source of leaking and occurrence in the environment and reduce the risk of health damage.

The EU Commission commented that the action proposed in the consultation draft in 2007 was disproportionate. They pointed to the referenced emission figures in the impact assessment (which was sent out for public consultation in May 2007) and noted that the products covered by the proposed regulation amounted only to about 2% of the total quantities of lead.

It is correct, as the EU Commission notes, that the largest quantities of lead reside in metallic products, which are either already regulated or exempt from the proposal. Nevertheless, the products that would be covered by the proposal constitute a minimum of about 450 tonnes of lead, which is a significant potential source of discharge or emission of lead into the environment (fishing gear for consumers totals about 170 tonnes, which is about 50% of the total quantity of fishing gear). In itself, 450 tonnes is a significant quantity of a substance on the Priority List and for which national targets for eliminating or substantially reducing have been set. This is a significant quantity of a health and environmentally hazardous substance, which therefore constitutes a large potential source of discharge and emission into the environment. The regulation proposal may result in some increased costs but will result in a significant reduction in the introduction of lead into the environment and will reduce the risk of health and environmental damages. We are anticipating that the benefits will outweigh the costs on the basis of the expected positive effects the proposal will have for health and the environment. The proposal makes exceptions for use in areas where no alternative substances can be used or where the use of an alternative substance would result in significant costs. The proposal therefore does not go any further than necessary to fulfil the objectives we are seeking to achieve and cannot be considered disproportionate.

The strong increase in sales of consumer products with the greater selection and shorter useful life of products can increase the dispersion of hazardous chemical substances. It is not the intention for most products to give off substances during use. However, there are several examples that chemical substances can spread from products, so that the discharge will be protracted over time (the product's entire life cycle) and space (people are exposed indirectly via the environment), for example, as a result of a leak of significant quantities of lead from fishing gear lost in water every year. In addition, there is leakage from waste disposal sites where products containing lead are disposed of. Contrary to industrial point sources, diffuse discharges from products are more spread out in society and may sometimes be associated with substances present in materials with a long useful life. The knowledge about the mechanisms and the scope of diffuse discharges from products is imperfect.

With respect to a number of the products covered by the proposed regulation, among other things, paint, varnish, glue, jewellery, imported musical instruments, fishing gear and various plastic products (PVC) such as garden hoses, petrol canisters, wall paper, plastic boxes, electrical wires and plugs, the registered sales and discharge figures are not adequate. Increased imports of products, especially PVC products from countries that lack regulation in the area, may mean that products will constitute a more important source of lead discharges in the Norwegian market as we begin to gain control over more of today's most significant sources.

Several of the consumer products covered by the proposal are not defined as hazardous waste but are introduced to the normal waste stream. These products do not contribute directly to

discharges during the usage phase but constitute a problem primarily when they end up as waste. As waste, lead from the products may leak into the environment if not handled properly. Fishing gear left to remain in the ocean and in fresh water will leak lead into the environment over time. There is also a risk that it will be ingested by birds, fish and mammals in the fishing areas and may cause toxic reactions. Many of the relevant products are goods used in the building industry, which have a long useful life and which end up as demolition waste at a later stage.

Consumer products are an important source of uncontrolled dispersion of hazardous substances into the environment. Regulation of hazardous substances in consumer products is especially important since consumers lack the necessary knowledge about the health and environmental problems associated with the use and waste disposal of these substances. Consumers also do not have the requisite knowledge and opportunity to be able to protect themselves against the emissions and discharges. The reduction in the quantity of substances hazardous to health and the environment in consumer products is also an important step to reduce the quantity of waste containing hazardous substances.

5.1 Proposal for Regulation

It is proposed that consumer products containing lead and lead compounds should be regulated in the following manner, and that this regulation be included in the Regulation 1 June 2004 No 922 relating to restrictions on the manufacture, import, export, sale and the use of chemicals and other products hazardous to health and the environment (Product Regulation):

It is prohibited to produce, import, export and sell consumer products containing chemical lead compounds, when the content of the substance in the product's homogenous individual parts is greater or equal 0.01% by weight.

The prohibition in the first paragraph does not apply to:

- *Red lead for restoration of historic objects,*
- *Fuel for airplanes,*
- *Paint regulated under section 2-5 of the Product Regulation,*
- *Rust protection paint with less than 250 ppm lead,*
- *Anti-marine growth paint with less than 1250 ppm lead,*
- *Crystal and lead glass,*
- *Optical glass,*
- *Products manufactured of recycled glass, regulated in the third paragraph,*
- *Glazes and enamels on products, which must be assumed not to come into contact with food,*
- *Packaging, batteries as well as electrical and electronic products and equipment regulated under sections 3-11, 3-13 to 3-14 and 3-17 to 3-19 of the Product Regulation,*
- *Cosmetics regulated under Statutory Order of 26 October 1995 for production, import and offering etc. of cosmetics and body care products (Cosmetics Order).*

It is prohibited to produce, import, export and sell consumer products manufactured using recycled glass containing chemical lead compounds, when the content of the substance in the product's homogenous individual components is greater than or equal to 0.05% by weight.

It is prohibited to produce, import, export and sell consumer products containing metal lead compounds, when the content of the substance in the product's homogenous individual components is greater or equal 0.01% by weight:

- *Products for hobby purposes,*

- *Tea candles and other candles,*
- *Curtain weights,*
- *Products for decorative purposes, including jewellery,*
- *Products for roofing and coverage of buildings,*
- *Fishing gear for leisure use.*

The prohibitions in the first and third paragraphs shall not apply to food products, food packaging, fertiliser, tobacco, medicine, means of transport, permanently mounted equipment for means of transport and tyres and similar accessories for means of transport. The regulation shall also not apply to spare parts for consumer products made available for sale before [XX MONTH YEAR- date of entry into force].

Consumer products shall here refer to any product intended for consumers and which can reasonably be expected to be used by consumers, cf. the definition set out in section 2a of the Norwegian Act of 11 June 1976 No 79 Relating to Control of Products and Consumer Services (Norwegian Product Control Act). Homogenous individual parts shall here refer to a material that cannot be divided mechanically into various materials.

For consumer products this section shall prevail over other provisions in this regulation, unless otherwise provided in the present section.

6 Assessment of Other Measures

In Norway's assessment, the health and environmental effect that is sought to be achieved with the proposal cannot be achieved with less restrictive measures. In the following, we evaluate alternative measures to our proposed regulation.

The proposal is motivated, among other things, by the consumer's lack of knowledge about health and environmental problems linked to the use of products, which may contain hazardous substances; how consumers need to protect themselves against potential exposure from these; how the products should be handled once they end up as waste. The question may be raised if this is a problem that can be solved through information campaigns directed at consumers. However, based on OECD studies and other research, all experience shows that information campaigns are not sufficient to reduce discharges of prioritised hazardous substances. The measure is too diffuse and too uncertain to reach the necessary goals. Information campaigns are therefore not a relevant alternative to the proposed regulation.

From Norway's perspective, a corresponding health and environmental effect also cannot be achieved using economic measures, such as a tax. A tax is most appropriate in cases where the only aim is to reduce the use of the substance and in cases where there is no urgent need to reduce the discharges. As a result of lead's health and environmentally damaging properties, it is important that we have a reduction in use and discharges or emissions that is as rapid as possible. This means that a tax is not a desirable measure. Economic measures have generally turned out to be less effective than usage and sales restrictions to achieve reductions in discharge. It would also be very difficult to establish a tax system that could produce the same effect as the proposed regulation. The large number of possible use areas would make it especially complicated to design and enforce a tax system.

It is also insufficient to introduce measures at a later stage of the sales chain. Return schemes would, for example, be less restrictive on trade than a regulation but would not lead to the same health and environmental impact. Regulation at the discharge source is the most effective regulation method when the objective is to achieve rapid reductions in discharges or

emissions. If measures are introduced at a later stage, once the products have been put on the market, it is more difficult to introduce measures that effectively prevent uncontrolled dispersion of prioritised hazardous substances. Furthermore, the risk of leaks and emissions would be greater once the reducing measures are introduced after the products have entered the market. It would be more effective to regulate near the source. Many consumers lack the relevant knowledge about return schemes. It is difficult enough to monitor that consumers are using the already existing return schemes.

Also, restrictions are a far more effective measure than labelling of products containing lead. It is not likely that labelling in itself will reduce the risk of dispersing or exposure of lead.

Voluntary agreements between the authorities and the industry have been effective measures in other environmental areas, among other things, in order to ensure proper waste handling. In this instance, where the purpose is to achieve a rapid reduction in emissions, voluntary agreements are, however, a far more uncertain measure than introduction of restrictions. Furthermore, lead is present in a large number of imported products. These are difficult to capture with voluntary agreements. The proposed restrictions will therefore be a more effective measure to achieve the desired result.

7 Impact Assessment

The proposal for regulation of lead in consumer products will reduce sales of lead with about 5% (approx. 450 tonnes lead annually) of the quantity currently registered. Even if 5% is a relatively small percentage share, cumulatively this is a significant quantity. Additionally, a significant reduction is expected of lead in imported solid products, over which we do not have a full overview of the quantity and scope. This also applies to, among other things, a large and varied range of plastic products, plastic-coated textiles, jewellery and painted products.

By removing consumer products with lead from the market, potential discharges and the risk of health and environmental damages will be reduced significantly.

7.1 Benefits

There are environmentally and economically acceptable alternatives to lead for the areas for which regulation is proposed. Regulation of lead in consumer products may lead to beneficial effects, such as reduced health and environmental damages related to reduced lead impact, but these are very difficult to quantify.

Health:
Generally, the risk of damage to health, both acute damage and chronic effects, will be reduced by removing lead from consumer products on the market. Benefits may be attained—but are not possible to quantify—in the form of reduced morbidity in the population and reduced costs related to this.

Beneficial health effects:
- Direct beneficial health effects are attained by having the risk of acute poisoning be reduced markedly, since jewellery and crayons with lead are prohibited and removed from the market.

- By prohibiting lead in fishing gear for leisure fishing, the risk of damage to health which may arise in connection with exposure in connection with casting/recasting fishing gear will be reduced.
- A similar effect is achieved by prohibiting materials containing lead for hobby use, such as soldering, casting and painting.
- The indirect beneficial effect to health will be achieved if lead is taken out of products. This means that lead that can be accumulated in the food chain will be reduced and it will be less likely that human beings ingest lead through food and drinking water.

Environment:
Positive environmental effects of regulating lead in consumer products will be that the amount of lead that can leak out and be accumulated in the environment will be reduced significantly.

Beneficial environmental effects:
- Birds and fish can be harmed directly or indirectly through uptake of lead left in nature. This may reduce numbers and species. It is a goal that biodiversity should be maintained and reduction of lead in the environment can contribute to this.
- In the long term, the regulation on lead will reduce the amount of lead in runoff from waste deposit sites (in leachate), which goes to both municipal processing plants and separate processing plants for rivers, streams and fjords. Leachate from about 75% of the waste disposal sites with discharge permits does not pass through municipal processing plants. The risk of diffuse dispersion of lead will be reduced.
- In connection with chemical recovery of materials, lead can be released and end up in a waste fraction and thereby be released into the environment via air or water. If lead is removed in consumer products, the quantity of lead from waste fractions to the environment will be reduced.

Other:
It is a goal to recapture and reuse the greatest possible amount of waste fractions that are produced. For that to occur, it is a precondition that these fractions do not contain priority substances. In doing so, the risk of health and environmental damages linked to products of recaptured material will be reduced and the use of new raw material resources will be reduced.

Positive effects:
- The quantity of lead in slag and ashes from incineration plants will be reduced and increase the risk that this will be used in products.
- Currently, PVC plastic containing lead can go to recovery. Recycled material containing lead can then be mixed with new PVC, which means that lead can be distributed in major quantities in new PVC products. Reduced quantities of lead in plastic will increase the opportunities for recycling plastic into new products without lead.
- If the PVC material contains lead compounds that exceed the limit for hazardous waste, it must be delivered to an authorised reception site and processed separately. If lead is removed from PVC, this will provide an opportunity to reduce costs for future waste management.
- Climate Cure 2020 has studied a number of measures and initiatives, which may contribute to reaching the national goal for emissions of climate gasses in 2020. There is a proposal for a 40% material recycling of all plastic. It should be impossible to recycle materials from plastic containing prioritised hazardous substances. The proposal for regulating lead in consumer products will be an important initiative toward reaching the goal of having sufficient plastic without these substances.

7.2 Costs

It is exceedingly complicated to obtain information about the lead content of the very significant number of products on the market in Norway. The Norwegian Product Register contains information about chemical substances and products (mixtures). However, this register contains no information about the content of substances in solid and processed products. Additionally, it is very complicated to estimate discharge and emission levels for these products, their dispersion into the environment, and to estimate which health and environmental damages will arise as a result of this. We have principally based our assessments on existing reports on use areas, consumption areas and impacts.

A limited number of companies use lead in their production in Norway. However, there are many importers importing products that may contain both metallic lead and lead compounds. A large part of the products with lead are produced in countries outside of Europe.

The PVC industry in Norway has largely phased out use of lead in its production. Within the EU, goals have been established that lead be phased out as stabiliser in PVC before 2015.[16] An impact assessment was previously carried out in connection with possible regulations for the phasing out of lead in PVC.[17] It concludes that the benefits outweigh the costs. However, it is difficult to quantify the costs savings of reduced health risks and waste management. With respect to reduced costs for waste treatment of materials containing PVC, the following conclusions have been reached:

> "Phasing out of lead from PVC can contribute to better and more cost-effective processing solutions in the future. The increased quantity of PVC waste may create a need for more restrictive waste management practices. If the opportunity for recovery (of PVC containing lead) and incineration (generally for PVC) are limited, disposal will be the only option for PVC products containing lead. Disposal requires a lot of space, is costly, and is a processing method that generates conflict. It is therefore not desirable."

Other assessments have been carried out of the costs related to phasing out products containing lead, among other things, fishing gear and candlewicks.[18] Fishing gear for consumers is being produced by a lot of small enterprises in Europe, and it is therefore difficult to have an overview of the scope. It also looks as though this type of production will be moved to a low-cost country in, among other places, Asia.

The reports conclude that the costs of replacing lead in fishing gear for consumers with other materials may become somewhat higher. Experiences from Denmark and the United Kingdom, which have regulations in this area, as well as a study from Sweden, indicate that the price for consumers will increase by an average of about 20% in the transition to alternative materials. It is reasonable to assume that this will also be the case in Norway. Former Norwegian producers of fishing gear for private use have moved their production

[16] www.vinyl2010.org
[17] COWI, 2001: Impact study of potential regulation for the phasing out of lead in PVC [Konsekvensutredning av mulig forskrift om utfasing av bly i PVC].
[18] Swedish Chemicals Agency, Bly i varor [Lead in products], Report 3/09 and COWI, Final Report November 2004: Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers and candlewicks.

abroad. In several products, lead has been replaced with alternative materials, among other things, tin, brass, copper, steel and plastic.

Candles with wicks containing lead are imported from countries outside the EU/EEA. This is probably a very small share of the total use of candles with wicks, but a regulation would remove this potential source of exposure. Regulation of lead in candlewicks is not assumed to result in costs for either consumers or producers/importers in Norway and the EU.

Denmark has had similar regulations for lead since 2002. This indicates that it is completely feasible to regulate the area and that good alternatives are present in the market without great socioeconomic consequences. There is every reason to assume that the socioeconomic conditions in Norway are not significantly different than in Denmark.
In advance of the revision of the Danish regulation, an impact assessment of potential amendments was carried out. A special assessment was performed for areas for which exemptions had been granted in the regulation, as well as for areas/product groups for which applications for dispensations has been received. The conclusion was that an adjustment could be carried out with increased benefits without major impact as regards costs. The scope of application was expanded in 2007.

7.3 Other Effects

Regulating lead in consumer products will likely have a very small impact on Norwegian industry, and will therefore not have any significant impact on employment. For companies exclusively based on import and sale of products containing lead, it will have financial consequences if they lose market share and do not manage to readjust to importing and selling lead-free products.

The administrative costs related to the proposal are considered to be low but there will be a need for follow-up and monitoring. The proposal for regulation will have a positive impact on companies producing, importing and selling alternatives.

7.4 Summary and Conclusion

Lead is a highly prioritised substance, for which a national target for eliminating the substance by 2020 have been set. Registered Norwegian sales of lead in products are significant, about 9,000 tonnes annually, of which a minimum of 5% (approx. 450 tonnes) in consumer products is covered by the proposal. A significant part of this is lead in imported products. This constitutes a potential source for the emission or discharge of lead, especially in the waste phase. Norwegian producers have reduced the use of lead in their production significantly. Information about lead in imported products is imperfect. Monitoring and analyses show that lead occurs in consumer products. The amount of lead in many of these products is not captured in the statistics of products containing lead. Even if the occurrence of lead in the environment has been reduced in recent years, measurements from leachate from waste disposal sites show that lead is being introduced to the environment. It is reasonable to assume that the sources for this are consumer products disposed as waste.

There is uncertainty linked to assessments of benefits and costs. This means that it is also not feasible to put numbers on the costs. With respect to costs for the industry linked to a potential regulation, we know that there are products without lead in the market for most of the use areas for which regulation is proposed. Based on the data gathered about alternatives and experiences and studies from other countries, it is our belief that introducing the proposed

regulation will not result in any significant socioeconomic costs. It is a precondition that exemptions be granted for certain areas. The proposal makes exceptions for uses for which no alternatives exist or where these involve significant costs.

The proposed regulation is linked to limit values and applies to specific use areas with exceptions. The exemptions have been proposed because some use areas are already strictly regulated, among other things, pursuant to the EEA Agreement, a lack of real alternatives, limited health and environmental impact of including the use area or that a regulation for this use area must be expected to result in significant costs. This modification will also simplify the implementation and thereby reduce the costs for industry and the trade. In drafting the regulation, we have emphasised reducing costs as much as possible without affecting the proposal's environmental effectiveness too greatly.

Broad regulation of the use of lead in consumer products will be the best means to reach the national target for elimination. Using economic means will be less relevant because there is a desire to reduce the discharges significantly in a short time. A tax system to regulate lead in various forms in that many different products, both as chemicals and as ingredients in imported solid, processed products would be very difficult to design and not least to enforce.

The proposed regulation will reduce the remaining quantity of discharge of lead from products and reduce future costs related to waste processing. Emissions into the environment occur mainly in connection with waste processing and—on the basis of the products' long useful life—the effects of a phasing out will not manifest themselves for many years to come. The beneficial effects in the form of reductions in releases, health and environmental risks and costs related to waste management will benefit future generations.

From Norway's point of view, there is no secondary legislation (EU/EEA regulations or directives) preventing a national regulation of lead in consumer products. Neither the rules set out in the EEA Agreement's main part nor the case law of the EU Court are considered hindrances to the proposal to regulate. We refer here to what has been stated about the special health and environmentally hazardous properties of the substance as well as the special risk lead constitutes to health and the environment when it occurs in consumer products. The proposed regulation is considered to be based on legitimate concerns (health and environmental concerns) and is considered an appropriate and necessary measure to reach the objective of reduced discharges of lead from consumer products. The measure goes no further than necessary to achieve the objectives we seek to achieve, *cf.* the impact assessment and previous statements relating to the proportionality of the measure.

8 References

- Advantage of limiting the use of lead in a number of consumer products, ISBN-NET: 978-2-11-097006-0
- Chapter 9, Norwegian Regulation on the Recovery and Treatment of Waste, Guideline TA No 2077/2005.
- COWI, 2001: Impact study of potential regulation for the phasing out of lead in PVC [Konsekvensutredning av mulig forskrift om utfasing av bly i PVC].
- COWI, Final Report November 2004: Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers and candlewicks.
- Evaluation of the Danish Statutory Order on Lead, Danish Ministry of the Environment—Environmental Protection Agency, Environmental Project No 1080 2006.

- Regulations relating to a framework for water management (Water Regulations), Annex VIII (EU Water Framework Directive).
- Swedish Chemicals Agency, Bly i varor [Lead in Products], Report No 3/07.
- Environmental impact assessment of potential regulations for the phasing out of lead in PVC, Norwegian Pollution Control Authority (SFT), TA 1964/2003.
- Monitoring and Measurements
    - Atmospheric fallout of heavy metals in Norway: National Study in 2005.
    - Elvetilførselsprogrammet http://www.klif.no/program____37064.aspx
    - http://www.imr.no/temasider/havomrader_og_okosystem/barentshavet/forvaltningsplan/nb-no
    - http://www.mareano.no/start
    - http://www.nifes.no/sjomatdata/
    - Prioritised hazardous substances along the coastline (CEMP) http://www.klif.no/program____37067.aspx
    - National Lake Survey 2004–2006, Part I: Water Chemistry. Status of acidification, nutrients and metals.
    - National Lake Survey 2004–2006, Part II: Sediments. Contamination with metals, PAH and PCB.
    - National Lake Survey 2004–2006, Part III: AMAP. Status of metals and environmental pollutants in lakes and fish from the Norwegian part of the AMAP region.
      Monitoring of Long-range contaminated air and precipitation. Atmospheric introduction, 2008.
- Poul Bo Larsen, Danish Environmental Protection Agency: Statement to Jyllandsposten.
- RAPEX 2006, Week 12, 0191/06.
- "Prioriterte miljøgifter – Status i 2008 og utslippsprognoser" [Prioritised Hazardous substances – Status in 2007 and Discharge Prognoses].
- TA No 1478/1998, Classification of Environmental Quality in Freshwater.
- UNEP Interim Review of Scientific Information on Lead and Cadmium, October 2006.
- www.vinyl2010.org