ROADMAP			
TITLE OF THE INITIATIVE	**Commission Regulation amending annex II, part III of Directive 2009/48/EC on toy safety (TSD)**		
TYPE OF INITIATIVE	Delegated act		
LEAD DG – RESPONSIBLE UNIT	DG ENTR- F3		
EXPECTED DATE OF ADOPTION	2011-2012		
VERSION OF ROADMAP	No: 1	Last modification:	

This indicative roadmap is provided for information purposes only and is subject to change.
It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context, problem definition

(i) What is the political context of the initiative?
(ii) How does it relate to past and possible future initiatives, and to other EU policies?
(iii) What ex-post analysis of the existing policy has been carried out and what results are relevant for this initiative?

(i)(ii)The new Toy safety directive 2009/48/EC (TSD) revised and modernised the legal framework for toy safety in the EU. Applicable as of 20 July 2011 (for the chemical requirements a longer transition period has been foreseen, namely 20 July 2013) the TSD will increase the level of safety for toys while ensuring their free movement on the market.

The new TSD introduces stricter requirements for chemical substances in toys compared to Directive 88/378/EEC, and allows for a constant alignment of these requirements to the latest scientific developments by means of amending the chemical provisions in the comitology procedure (regulatory procedure with scrutiny). The Commission can propose amendments to certain chemical requirements when new scientific data is made available. This initiative is such a proposal.

In particular, the TSD contains specific migration limits for lead, based on scientific evidence available in 2008 at the time of the legislative procedure. The current migration limits build on the RIVM[1] report and on different scientific opinions and are based on the Tolerable Daily Intake (TDI), the weight of a child and the toy material ingested. A specific percentage of the TDI is allocated to toys, meaning that intake from toys can not exceed 5 or 10 % of the daily intake (from all sources foods and non food products included).

For lead in particular, the migration limit is based on the TDI derived from the Tolerable Weekly Intake of 25 µg/kg b.w established by JECFA (Joint FAO/WHO Expert Committee on Food Additives) in 1986 (reconfirmed in 1999) and endorsed in 1992 by the European Commission's Scientific Committee for Food (SCF). A 5% allocation of the TDI was considered for toys, meaning that only 5% of the lead daily intake can come from toys (the rest of the intake comes from other sources). At EU level, the presence of lead in ceramics and plastic materials which came into contact with food is already restricted. Lead carbonates and sulphates are restricted for use in paints. Measures are under preparation for restricting the presence of lead in jewellery.

(iii) The limits for lead contained in Directive 88/378/EEC have been updated in the framework

[1] Dutch National Institute for Public Health and the Environment, 2008

of the revision of the abovementioned directive, in order to take into account the scientific development.

What are the main problems which this initiative will address?
Lead is a particularly toxic metal which takes both organic and inorganic form. Given that lead is considered as a non-threshold toxic substance for neurotoxic effects and given the specific vulnerability of children, their exposure to lead should be reduced to the maximum extent possible. The exposure to lead can cause damage to a child's central nervous system, thus adversely impacting his/her development. Lead exposure mainly arises from food products (cereals, vegetables and tap water being the major contributors to lead exposure). Another important exposure source is the environment, in particular house dust. An additional exposure source is the contact with consumer products, including toys. Given the high exposure from food and environment, limit values for lead in toys were set out in such way that exposure from toys can not exceed a certain amount of all exposure sources. Lead may be found in toys paints and softened plastic. Children are exposed to lead through ingestion, in particular through hand-to-mouth or mouthing behaviour. As paint deteriorates, it peels, pulverizes and then can be ingested or remains on the hands and fingers from where it can be ingested or inhaled. Considering lead toxicological characteristic, the dermal exposure does not seem to represent any health risk. The latest EFSA study[2] on Lead in Food concluded in 2010 that the current Provisional Tolerable Weekly Intake of 25 µg/kg b.w is no longer considered appropriate for calculating limit values for lead due to the impossibility to establish a threshold below which no critical effect on health can be observed. The study took into consideration an updated exposure assessment for lead, addressing in particular exposure from food (including drinking water) and from other non-dietary sources (e.g. air), the exposure situation for specific groups of the population (e.g. infants and children, etc.) and an indication of the age group in which children would be most exposed to the toxic effects of lead. While acknowledging that further research is necessary, EFSA recommended reducing the lead exposure from both food and non foods products. As this new scientific evidence shows, the level of protection of children against exposure to lead, as established in 2009, is no longer appropriate. Therefore, it is necessary to amend the current values for lead and align them with the latest scientific data, in order to reduce children's exposure.
Who will be affected by it?
Potential measures on reducing the presence of lead in toys will affect the EU toy industry (manufacturers, importers, distributors). Manufacturers outside the EU will also be affected, as they have to comply with the EU legislation when placing toys on the EU market. Member states will be affected because they have to implement the new rules and therefore conduct appropriate controls. Testing laboratories will be affected as they need to have appropriate testing facilities, machineries and test methods in place. The lower the values, the more crucial the accuracy of testing will be.

[2] European Food Safety Authority opinion on lead in food (EFSA Journal 2010; 8(4):1570)

Children playing and being exposed to toys containing lead traces are the main beneficiaries of the potential measures. The level of exposure to lead from toys will be reduced, resulting in an increased level of protection for children. On the other hand, as lead is present in the environment and is often a natural contaminant in certain toy materials, some toys may be banned from production (such as colouring pencils, chalks, wax crayons, pastels or in water paint tablets).

(i) Is EU action justified on grounds of subsidiarity?
(ii) Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? (Necessity Test)
(iii) Can the EU achieve the objectives better? (Test of EU Value Added)

The objective of the initiative is to ensure a high level of safety of children whilst guaranteeing the functioning of the internal market (article 114 TFEU). Individual actions undertaken by MS could lead to a fragmentation of the internal market and create barriers to trade in toys. Therefore, uniform rules set at the EU level are more appropriate. Further more, so far limit values for chemicals in toys have always been set out at EU level. Potential changes to limit values adopted at EU level can only be done at the same level.

B. Objectives of the initiative

What are the main policy objectives?

The initiative has two general objectives: (1) to ensure a higher level of safety for children by reducing the exposure of children to a particularly toxic substance and (2) to ensure a proper functioning of the internal market for toys. More specifically, the aim is to align the current limits for lead with the latest scientific evidence.

Do the objectives imply developing EU policy in new areas?

No, the objectives do not imply developing EU policy in new areas or in areas of strategic importance.

C. Options

(i) What are the policy options being considered?
(ii) What legislative or 'soft law' instruments could be considered?
(iii) How do the options respect the proportionality principle?

1. No policy change

This option would imply maintaining the current limits for lead as they were established in 2009, on the basis of the best available scientific data.

2. Soft law / self regulatory approach

This option would imply inviting the industry to put in place voluntary agreements on reducing the lead limits in toys.

3. Partial revision of the current limits

This option would imply reducing the current limits for lead only in certain categories of toy materials according to the latest scientific evidence. Other categories of toy materials from natural sources such as clay, caolin, or pigments used in coloured pencils, chalks, wax crayons, pastels or in water paint tablets would be exonerated, because they are naturally contaminated with lead occurring in the environment.

4. Complete revision of the current limits

This option would imply reducing the current limits for lead in <u>all</u> categories of toys and toy material according to the latest scientific evidence.

A phased introduction of new limits, which would give more time to economic operators to comply, was considered. However, such option would not be feasible, as certain materials would never comply with stricter limits, because they are naturally contaminated with lead occurring in the environment.

D. Initial assessment of impacts
What are the benefits and costs of each of the policy options?
The "No policy change" option will not bring any improvement to the protection of children's health. Options 2, 3 and 4 are likely to improve the protection of children. However, they differ in the degree of reducing the children's exposure to lead, as well as in the implementation costs. 1. Children will continue to be exposed to lead and this exposure may lead to damage to their central nervous system. No new costs are foreseen for the industry and market surveillance authorities, but the risks of children's health are higher than in the case of the other options. 2. Soft law, guidelines or self regulatory approaches may present some advantages for the economic operators, but are most of the time inefficient, because of their non binding character. Limited costs are expected for the industry and market surveillance authorities, as well as a limited increase in the level of children's protection. 3. Partial revision of the current limits would avoid the potential ban from the market of certain toys, such as coloured pencils, chalks, wax crayons, pastels or in water paint tablets, because for these categories the values would remain unchanged. Limited costs are expected for the industry, test laboratories and Member States. However, the exposure of children to lead would not be reduced for all toys. 4. Complete revision of the current limits will present the highest benefits as it would result in a higher protection of children from lead exposure by lowering the levels of lead which may be found in toys. However, this option may also imply a significant negative impact on the competitiveness of the relevant parts of the EU industry as it may come at a significant cost to the industry - certain categories of toys and toy materials might be completely banned from production. Testing laboratories will be affected as they need to have appropriate new testing facilities, machineries and test methods in place.
Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?
(i) No impact on simplification is expected. (ii) No additional impact on administrative burdens is expected. (iii) Economic operators from third countries are obliged to comply with the EU legislation when placing toys on the EU market. Therefore, they might face significant costs under policy option 4. (iv) For policy option 4, difficulties may be expected in terms of implementation at the EU level. Market surveillance authorities will implement the measure by means of laboratory testing. Laboratories are using detection limits to test the presence of chemical substances in toys. These detection limits can vary from test laboratory to another, resulting in different limits used as tolerable between Market surveillance authorities. The lower the values, the more difficult the accuracy of testing will be. This could lead to a distortion of the market. Testing laboratories in the EU use different detection limits for cheeking if a toy contains restricted chemical substances. Once the chemicals are found, the testing laboratories proceed to checking if the limits set out in the legislation are respected. When the legal limits are too low, certain laboratories may not detect the chemical substances, depending of the detection limits they are using.
(i) Will an IA be carried out for this initiative and/or possible follow-up initiatives? (ii) When will the IA work start? (iii) When will you set up the IA Steering Group and how often will it meet? (iv) What DGs will be invited?

(i) An Impact assessment will be carried out for this initiative. It will be finalised in the first half of 2012

(ii) The Impact assessment process will start in June 2011.

(iii) The Impact assessment steering group will be set up in July 2011 and will meet three times. The meetings will be organised in the second half of 2011 and first half of 2012.

(iv) Directorate General Health and Consumers, DG TRADE, DG ENVI and the Secretariat – General will be invited to participate.

(i) Is any of options likely to have impacts on the EU budget above €5m?

(ii) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial regulation? If not, provide information about the timing of the ex-ante evaluation.

No impact on the EU budget is expected.

E. Evidence base, planning of further work and consultation

(i) What information and data are already available? Will existing impact assessment and evaluation work be used?

(ii) What further information needs to be gathered, how will this be done *(e.g. internally or by an external contractor)*, and by when?

(iii) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?

(iv) Is any particular communication or information activity foreseen? If so, what, and by when?

Some information and data was already made available by the industry representatives. However, additional detailed data is needed. The restriction of the use of lead in jewellery was already assessed in the Report on the proposal for a restriction of lead in jewellery, carried out in the framework of the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Regulation 1907/2006. The findings of this document may be used in the framework of lowering the limits for lead in toys.

Additional information on materials used, testing and production methods need to be collected from the industry. This information will be gathered both internally and externally, in the process of stakeholders' consultation. An external study will be contracted in order to gather specific information related to the competiveness impacts on the toy industry.

No particular communication or information activity is planned for the moment.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

Member States, industry and consumers associations received information on the initiative via the Expert group on toy safety gathering all involved stakeholders. Some comments were already gathered via this channel. A public consultation of all involved parties via IPM is foreseen for the second half of 2011.