

# COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE COUNCIL

THE RISK OF DAMAGE TO HEARING

RESULTING FROM NOISE EMITTED BY TOYS

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A report made by the Commission to Council in accordance with its undertaking given on the occasion of the adoption by Council of Directive 88/378/EEC of 3rd May 1988, concerning the safety of toys (O.J. No. L187 of 16.7.88, pages 1 to 13).

SUMMARY

1. When Council adopted the Toy Safety Directive (88/378/EEC), the Commission undertook to report, within approximately 18 months, on the available scientific evidence regarding damage to hearing from noise emitted by toys.
2. A search of the available literature on this subject and recourse to certain expertise by the Commission have failed to establish scientific evidence on which an "essential safety requirement" (in the strict sense of that term appropriate to the "New Approach" to technical harmonisation now practised on the Community level) can be based.
3. The Commission will consider whether and to what extent the Community should encourage and support research designed to establish evidence of such risks as may exist to hearing from noise emitted by toys.
4. In the meantime the Commission will take advantage of the fact that the European Committee for Standardization (CEN) is in any case going to revise its standard EN71 Part 1 concerning the mechanical and physical risks of toys, and ask the CEN, as part of its revision, to lay down test methods for measuring noise intensity and certain specifications concerning noise from toys. As part of a standard these specifications would not be compulsory, but they would take account of the fact that the lack of scientific evidence does not rule out the possibility of damage to hearing from toys. The restrictions concerning noise peaks exceeding 200 pascals (140 decibels), as set out in Directive 86/188/EEC concerning exposure to noise at work, should be respected by that standard.

THE RISK OF DAMAGE TO HEARING RESULTING FROM NOISE  
EMITTED BY TOYS

I. INTRODUCTION

1. A statement in the minutes of the Council meeting of May 3rd, 1988 at which the Toy Safety Directive (88/378/EEC) was adopted, commits the Commission to "submit to the Council, within approximately 18 months, a Report based on available scientific evidence concerning the risks which toys may pose to hearing".  
It is further stated that "any proposals designed to add to this Directive an essential safety requirement" concerning noise levels in toys would follow from the use of this Report.
2. The Commission had previously requested CEN, by letter of January 27th, 1988, to make a survey of national standards in order to ascertain whether they dealt with this question. Only five members had replied by the date of adoption of the Directive, none of them reporting that they had established standards. Sweden and Denmark however, favoured the establishment of safety standards for noise from toys; the United Kingdom, while stating that it "had not identified particular problems with acoustical risks from toys" pointed to the U.S. standard for impulsive noise from toys (ASTM/F963/86) which the U.K. toys manufacturing association regarded as "suitable for incorporation within a harmonised European standard". The two other members (Germany and Italy) saw no need for concern regarding such risks. To the best of the Commission's knowledge, no further reports from members on this matter have since been received by CEN.

II. THE STATE OF SCIENTIFIC KNOWLEDGE

1. Following the adoption by Council, on May 12th, of a Directive "on the protection of workers from the risks related to exposure to noise at work" (86/188/EEC), the Health and Safety Directorate of DG V retained the services of a number of scientific experts to assist in monitoring "progress made in scientific knowledge and technology" with a view to meeting the requirement of Article 10 of the Directive that "The Council, acting on a proposal from the Commission shall re-examine this Directive before 1 January, 1994 ... with a view to reducing the risks arising from exposure to noise".

2. Following the adoption of the Toy Safety Directive, the Service concerned with industrial noise (DG V/E/1) agreed to ask its scientific experts to advise on the state of knowledge of risks resulting from noise emission from toys, having regard particularly to any information or opinion on the subject which might emerge from the proceedings of the then forthcoming major international conference on the effects of noise, due to be held in Stockholm in August, 1988.
  
3. The reports of the experts have yielded nothing of real substance concerning very young people. Only one of them (Dr. Passchleer-Vermeer) of the Netherlands Research Institute, INO) addressed the question of hearing loss in young people due to noise in general (having no basis on which to relate her remarks to toys in particular). In a letter dated December 21, 1988, to the Commission (DG V/E/1), she stated :
  - i) that "there was not any paper reporting on hearing in very young people" (at Stockholm);
  
  - ii) that she was currently occupied with a study on hearing of young people which, at that stage, only comprised an inventory of existing data;
  
  - iii) that, as a preliminary conclusion, unselected young populations in the Netherlands, not subject to occupational noise exposure, had the same threshold hearing levels as those determined for similar populations 25 years ago;
  
  - iv) that "hardly any data exist on the exposure patterns of young people to any of the potential hearing-damage sources, nor are there any data on combined exposures" and that it is unknown "whether there is a population at risk and, if so, what the size of the risk is and which part of the total population it concerns".

She concluded that "it is obvious that little is known about the effects of noise exposure on young people and on the noise exposures as such" and that "a discussion about the need of further research into the subject would be highly desirable".

4. The National Swedish Board for Consumer Protection commissioned a study in 1982 by the Department of Occupational Audiology in Gothenburg which comprised, on one hand, a search of the literature on hearing damage to children from noise emitted by toys, and, on the other, a series of measurements of the intensities of sounds emitted by various kinds of toy. The clinical evidence uncovered by the search was scant and inconclusive. The measurements of sound intensity at close range showed :

- a) that toys emitting continuous sound may reach levels of intensity exceeding those regarded as acceptable for adults industrial environments; and
- b) that toys containing explosive or other sources of impulsive sound may achieve peak intensities of sound emission exceeding the safe limits set for adults for impulsive sound under industrial conditions.

The measurements were made at distances from the sources of noise which were considered to approximate those at which children might hear them under the most unfavourable conditions (10 cm. for continuous noise and "squeaking" toys, 50 cm. for toy pistol caps and 3 m. for firecrackers).

The study concluded with recommendations for the limitation of intensities of emission of both continuous and impulsive sound to values specified therein and for the labelling of sound emission values on toys.

5. A more recent (1988) report from the same Swedish source concerns the effects on small animals (guinea pigs) of repeated exposure, at short time intervals and in close proximity to the sources, to explosive sound from toy pistols and firecrackers. Under the most severe conditions (100 explosions at intervals of 15 seconds and at distances of 0.25 metres and 0.8 metres, respectively, from the toy cap pistols and the firecrackers) most of the animals showed pronounced loss of sensory cells in the ear. Although the authors recognise the difficulty of extrapolating these results from animals to humans, they believe that their findings "are consistent with clinical experience in which it is common to find that individuals with a high-tone sensorineural hearing loss can vividly remember acoustic accidents, e.g. where a firecracker or toy pistol cap exploded close to their ear resulting in ..... at least a temporary hearing loss".

### III. APPRAISAL OF RISKS

A distinction should be made between chronic hearing loss which can occur gradually due to noise exposure over years or even decades, and acute quasi-traumatic damage which can occur as a result of very intensive (albeit short-lived) noise such as explosions.

Where chronic hearing loss is concerned :

1. Although the Swedish measurements under reference at II (4) above establish that noise-emitting toys may, under very unfavourable circumstances, produce intensities of continuous or impulsive sound exceeding those regarded as safe for adults, it is most unlikely that they will do so for sustained periods of time of a magnitude similar to that encountered over very short time intervals of the order, at most, of tens of seconds.
2. Periods of play indoors with noisy toys would seldom exceed a couple of hours as compared to the industrial working day of 8 hours.
3. When children play outdoors, the noise of toys is dispersed much more widely in the absence of the reflecting surfaces typical of indoor play situations.
4. It must also be remembered that noisy toys are operated by children themselves, whereas industrial noise is usually imposed on adults at work from sources over which they have little or no control. Children would be unlikely to sustain serious discomfort when they could themselves discontinue the noise at source. It is, of course, true that some children may impose sound emissions on others through play with toys but those receiving the sound in such cases usually can move away from the source of noise if it causes them discomfort, thereby reducing the received sound intensity immediately. Of course, it is impossible to rule out situations in which children generate noise without being aware of the possible risk, and a warning (to parents) could therefore be necessary.
5. In many cases, if noise from toys is electrically generated, its energy level will usually decrease rapidly with sustained use because batteries are, almost invariably, the source of electrical supply. The risk of sustained high-energy sound emission from such toys is therefore slight.

6. In her report, under reference in paragraph II (3) above, Dr. Passchloer-Vermøer said that a number of researchers had concluded "that the equivalent sound level (i.e. the weighted daily average intensity over 8 hours) is the most relevant noise measure to estimate noise-induced hearing loss, also in the case of impulse noise". This measure is the one used in Directive 86/188/EEC as the basis for establishing safe limits of noise intensity for persons exposed to it in work environments.
7. When all of these mitigating circumstances are taken together, it may be concluded that the "equivalent sound level" emitted by toys and received at the ears of children playing with them would, almost invariably, be a small fraction of the measured maximum intensities under reference in II (4) above, thus bringing them well below the levels of danger for noise-induced hearing loss.

As regards acute noise effects, it might be considered that acute hearing damage could result from exposure even to a very small number of very intensive noise impulses. It would therefore be wise to apply to children, as a matter of prudence, at least the restrictions of Directive 86/188/EEC which does not allow unprotected ears to be exposed at work to noise peaks in excess of 200 pascals (140 decibels).

#### IV. SHOULD AN ESSENTIAL SAFETY REQUIREMENT BE ESTABLISHED ?

1. It is certain that all interests associated with the manufacture and use of toys would support the principle that sound emitted by toys should not harm the hearing of children. It is a great deal less certain that any consensus would exist for the incorporation of this principle in the Toy Safety Directive in the form of an "essential safety requirement" explicitly scant scientific evidence now existing on the incidence of damage to hearing from this source.
2. The scientific evidence on which to base such an "essential requirement" is lacking because the research necessary to adduce such evidence has not been carried out. Suitable designs and specifications for such research have not even been prepared as yet, so far as is known from the available literature on the subject.

3. There is no scientific evidence that the tolerance to noise of young people's ears, or more specifically those of children up to 14 years (who are, by definition, the users of toys) is different from that of older age groups and, in these circumstances, the only reasonable assumption is that tolerance remains of the same order of magnitude at all ages except, perhaps, in early infancy, when the formative state of the human hearing organs might render them more liable to damage than they would in later years.
4. The absence of scientific evidence is not in itself a sufficient basis for assuming that noise emitted by toys is essentially harmless. Dr. Passchleer-Vermeer of TNO (see paragraph 11.3 above) advocates discussion of the need for further research and it may well be that such research would reveal specific circumstances in which hearing damage would occur.
5. The Commission will consider further, whether and to what extent, the Community should encourage and support research in this matter.

Meantime however it must respect the stipulation of the Council (see paragraph 1.1 above) that "any proposal designed to add to this Directive an essential safety requirement" should follow from the use of the scientific evidence reported.

It therefore appears that no specific requirement in respect of noise emission from toys can be added to Annex II of the Directive at present.

6. However, as the European Committee for Standardization (CEN) is in any case going to revise its standard EN71 Part 1 concerning the mechanical and physical risks of toys, the Commission could ask the CEN, as part of its revision, to lay down test methods for measuring noise intensity, certain specifications concerning noise from toys and requirements as regards safety warnings for those responsible for children (parents).

As part of the revised standard EN71 part 1, these specifications would not be compulsory, since CEN standards are voluntary. This is a reasonable solution which takes account of the lack of adequate scientific evidence to lay down compulsory legislative provisions and the fact that this lack of scientific evidence do not, however, rule out the possibility of damage to hearing from toys.

7. The Commission will base its request to the CEN on the general principles contained in Annex II, paragraphs 1 to 3 of the Directive, according to which users of toys should be protected against health risks. It will particularly direct the attention of the CEN to the provisions of the Council directive on protection against noise exposure at work (86/188/EEC) and to the American standard (ASTM/F 963/86), and ask it to at least comply with the restrictions of Directive 86/188/EEC as regards noise peaks exceeding 200 pascals (140 decibels). In fact the Directive and the American standard approximate very closely to the recommendations made in the study referred to in paragraph 11.4 above.
  
8. Specifications closely based on the foregoing provisions should, on the one hand, allay any reasonable doubt that may exist regarding risks of hearing damage from toys and, on the other, leave manufacturers with the degree of latitude they require for the manufacture of toys which have noise emission as an inherent characteristic.