

Lovens tittel:

Lov om produktansvar

Lovhjemmelens dato og nummer:

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Lovens fulle tittel og evt. korttittel på engelsk:

Act relating to Product Liability

Opplysninger om når loven sist ble endret:

Dato for oversettelsen:

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Oversatt av Peter Bilton

Eventuelle bemerkninger:

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Act no. 104 of 23 December 1988 relating to Product Liability
Cf. Annex III to the EEA Agreement (Council Directive
85/374/EEC). Cf. the earlier Act no. 18 of 9 April 1976
relating to international private law rules concerning
the choice of jurisdiction in connection with product
liability.

Chapter 1. Scope and definitions

§ 1-1.1) (scope)

(1) The present Act applies to the liability of a
producer²⁾ for damage caused by a product³⁾ made or supplied
for sale⁴⁾ as part of his profession, business or equivalent
activity.

(2) The Act does not limit the right to claim damages on
other grounds.

1) Amended by Act no. 113 of 27 November 1992 (see its
Chapter II, in force at the same time as the EEA
Agreement 1 January 1994).

2) See § 1-3 (1).

3) See § 1-2 (1).

4) See § 1-2 (2).

§ 1-2.1) (definitions)

(1) "Product" means all kinds of goods and movables
whether a natural product or industrial product, raw material
or finished product, part product or main product, also if the
product has been incorporated in another movable or in real
property. "Product" also comprises electricity. Waste
resulting from production is included if the waste is supplied
for sale as part of an activity as mentioned in § 1-1. Where
nothing else appears from the context, what is meant is the
specimen of the product which causes the damage.

(2) A product has been "supplied for consumption" when
it has been taken over or put to use by the injured party or
another consumer, or used on the injured party.

1) Amended by Act no. 113 of 27 November 1992 (see its
Chapter II, in force at the same time as the EEA
Agreement 1 January 1994).

§ 1-3. (who is liable)

(1) Liable as "producer" under the present Act is:

- a) anyone who manufactures or produces a product as defined
in subsection 1 of § 1-2,
- b) anyone who presents a product as his own by placing his
name, trade mark or other distinguishing mark on the
product or its packaging,
- c) a dealer in the product, when the producer is not easily
identifiable from the product and the dealer does not
within a reasonable time state the name and address
either of the producer or of a previous dealer,
- d) a dealer in an unprocessed natural product deriving from

fishing or trapping of wild animals or gathering of wild plants, when the supplier of such a product is not regarded as a producer according to litra (a),
e) the importer of a product imported from abroad,
f) a dealer in an imported product, if the name and address in Norway of the importer or intermediary distributor are not stated within a reasonable time.

(2) The King can by agreement with a foreign state lay down that imports into this country from one or more specified countries shall not be regarded as imports according to this Section, and that the person who has imported the product to one of the states parties to the agreement from another state shall be liable as producer.

(3) The present Act does not apply to an employee's liability for acts or omissions in an employer's service, with the exception however of § 3-8.

§ 1-4. (extent)

The Act does not apply in so far as the matter is to be decided according to foreign law pursuant to the Hague Convention of 2 October 1973 on the law to be applied to product liability. The Convention in Norwegian translation as published in the Norwegian Law Gazette¹⁾ has the force of law in this Realm, with the exception that paragraph 9 of Article 8 concerning statutory limitation does not apply.

1) Section 1 1976, pp. 167 ff.

§ 1-5.1) (exception for nuclear damage)

The Act does not apply to nuclear damage or other damage covered by the rules concerning liability for damages in Act no. 28 of 12 May 1972 concerning Nuclear Energy Activities or such corresponding foreign legislation as may be made applicable.

1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994).

Chapter 2. Liability

§ 2-1.1) (basis of liability)

(1) The producer²⁾ is obliged to pay compensation for damage which his product³⁾ causes because it does not offer the safety which a user or the public could reasonably expect (hereafter referred to as safety deficiency. In determining the degree of safety which could be expected, due account shall be taken of all matters relating to the product, its presentation, marketing and foreseeable use.

(2) The general assessment of the level of safety (safety standard) shall be based on the circumstances at the time when the product was supplied for sale.

1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994).

2) See § 1-3 (1).

3) See § 1-2 (1).

§ 2-2.1 (exceptions from liability)

The producer²⁾ is free from liability if he can show:

- a) that he did not supply the product for sale as part of his activities, or
- b) that the safety deficiency³⁾ did not exist at the time when the product was supplied for sale, and that no obligation applied to avert the damage or to minimize it afterwards, or
- c) that the reason for the safety deficiency was that the product satisfied rules issued by a public authority and indispensable in every respect.

1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994).

2) See § 1-3 (1).

3) See § 2-2.

§ 2-3.1 (The damage covered)

(1) The act applies to

- a) injury to persons, or
- b) damage to objects which
 - are of a kind normally intended for private use or consumption, and
 - were used by the injured party chiefly for his private use or consumption.

(2) However, the Act does not apply to:²⁾

- a) damage caused to the product³⁾ itself,
- b) damage which a part product causes to a product³⁾ in which the part product was incorporated or into which it was transformed before the product was supplied for sale to a user.

(3) When compensation for damage to an object is fixed according to this Act, a deduction shall be made amounting to NOK 4,000.-.

1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994).

2) Cf. §§ 40, 67 and 84 of Act no. 27 of 13 May 1988.

3) See § 1-2 (1).

§ 2-4. (part producer etc.)

(1) When damage is due to a safety deficiency¹⁾ in a raw material, semi-finished product or other product²⁾ (part product) which at the time of the damage was incorporated in a main product, both the producer³⁾ of the part product (the part producer) and the producer³⁾ of the main product (the main producer) are liable.

(2) The part producer is nevertheless free from liability if he can show that the safety deficiency¹⁾ in the part product must be attributed to the main producer's design, construction or specification, and that he cannot be blamed

for adhering to them.

- 1) See § 2-1.
- 2) See § 1-2 (1).
- 3) See § 1-3 (1).

§ 2-5. (calculation, reduction)

Amounts of damages are decided on, calculated and reduced according to the general rules governing damages, cf. Act no. 26 of 13 June 1969 relating to Damages.

§ 2-6. (disclaimer of liability)

Agreements restricting or limiting liability under this Act are invalid.

§ 2-7.1) (statute-barring)

(1) A claim for damages according to this Chapter becomes statute-barrred three years from the date when the injured party obtained or ought to have obtained the necessary knowledge of the damage, the safety deficiency²⁾ and who the producer³⁾ was.

(2) The claim becomes statute-barrred in any event at the latest ten years after the date when the producer³⁾ supplied the product⁴⁾ causing the damage for sale.

(3) Otherwise the rules in Act no. 18 of 18 May 1979 relating to the Limitation of Claims apply as appropriate.

- 1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994). - Cf. § 9 of Act no. 18 of 18 May 1979.
- 2) See § 2-1.
- 3) See § 1-3 (1).
- 4) See § 1-2 (1).

Chapter 3. Special provisions relating to drug liability

§ 3-1. (scope of the special provisions)

(1) Personal injury caused by a drug¹⁾ (drug injury) or during the testing of a drug (test injury) is indemnified according to the provisions in this Chapter, in so far as Norwegian law is applicable (cf. § 1-4).

A test injury is any injury caused by a test, for instance by the drug itself (drug injury), by the test procedure, by the taking of special samples, by special uses of technical equipment or by special treatment in connection with the test.

(2) If the drug causing the injury had not been supplied for consumption²⁾ in this Realm, the provisions only apply in so far as the injured party was resident here and the same drug brand manufactured by the same producer had at the time of the injury been supplied for sale or approved for registration here.

(3) The provisions in Chapters 1 and 2 apply correspondingly to drugs as appropriate and provided they do not conflict with the provisions in this Chapter.

1) See § 3-2.

2) See § 1-2 (2).

§ 3-2. drug

(1) For the purposes of the present Act, "drug" means a product which is regarded as a drug pursuant to Act no. 5 of 20 June 1964 relating to Drugs etc., and is intended or sold for human use.

(2) As "drugs" are also reckoned other products¹⁾ which are used in experiments on humans as a stage in the development of drugs. The King can in regulations lay down that a product¹⁾ for special medicinal use or for other special use in health care and nursing shall be equated with drug.

1) See § 1-2 (1).

§ 3-3.1) (basis for liability and exceptions to insurance cover)

(1) Drug insurance according to § 3-4 indemnifies injury according to the present Chapter regardless of whether the producer, importer or other person under an obligation to take out insurance is to blame for the injury or responsible for a safety deficiency²⁾ according to Chapter 2.

(2) Except in cases where the injury is due to a safety deficiency²⁾ in the drug which carries liability according to Chapter 2, damages are nevertheless not payable in so far as the injury

a) is a consequence of a wrong delivery or a mistake of drugs or other negligence at a pharmacist's, at a doctor's surgery, in a hospital, or by another distributor,

b) was caused in some other manner than by the foreseeable use of the drug, including use contrary to a properly issued and specific warning or incorrect use owing to neglect on the part of the physician in the form of a wrong prescription or inadequate advice,

c) is a consequence of the drug's lack of effect or lack of sufficient effect, or

d) is due to side-effects which, in view of the injured party's situation, it is reasonable for him to take the consequences of. In this assessment, emphasis shall be given to his health before use, the importance of the drug to his illness, the anticipated and actual effects of the drug, the nature and extent of the injury and the other circumstances of the case.

3) The exceptions in litra (a) or (b) of subsection 2 do not apply, however, to test injuries⁵⁾.

1) Amended by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement 1 January 1994).

2) See § 2-1.

- 3) Cf. § 33 of Act no. 17 of 21 June 1963.
- 4) Cf. § 5 of Act no. 42 of 13 June 1980.
- 5) See § 3-1 1).

§ 3-4. (drug insurance)

(1) A producer of a drug¹⁾ is obliged through membership of the Drug Liability Association (cf. § 3-5) to be insured against drug liability according to the present Chapter. The same applies to a drug importer if the producer does not have such insurance. This insurance (Drug Insurance) applies directly for the benefit of the injured person. Drug Insurance also covers injury caused by an anonymous or uninsured²⁾ drug. The King can permit only limited insurance to be taken out provided sufficient guarantees are furnished instead to cover the excess liability.

(2) Anyone engaged in carrying out tests on humans as a stage in the development of drugs¹⁾ is obliged²⁾ to have such insurance as is mentioned in the first paragraph if neither the producer nor the importer of the drug has such insurance as also covers the test.

(3) Drug Insurance is taken out with an insurance company or a pool of jointly and severally liable insurance companies. The insurance company, the insurance scheme and the terms and conditions of the policy must be approved by the King³⁾.

(4) The King can issue regulations relating to insurance in connection with imports of certain types of drugs, and can make exceptions or lay down special import rules in individual cases.

- 1) See § 3-2.
- 2) Cf. § 3-8 (2).
- 3) The Ministry of Justice according to Royal Decree no. 1065 of 23 December 1988.

§ 3-5. (the Drug Liability Association)

(1) Producers and importers of drugs¹⁾ which are sold in Norway must in order to be permitted to carry on such activities be members of an association of such producers and importers (the Drug Liability Association)²⁾. The same applies to others who, when engaged in the development of drugs¹⁾ are obliged to have insurance according to § 3-4.²⁾ The Drug Liability Association shall have statutes approved by the King³⁾.

(2) The Drug Liability Association is responsible for seeing that mandatory drug insurance is taken out according to § 3-4. It can take out collective liability insurance on behalf of its members.

- 1) See § 3-2.
- 2) Cf. § 3-8 (2).
- 3) The Ministry of Justice according to Royal Decree no. 1065 of 23 December 1988.

§ 3-6. (limitations of drug liability)

(1) Total indemnity according to the present Chapter

shall not exceed NOK 30 million for injuries ascertained in the same calendar year. An injury is regarded as ascertained¹⁾ from the time when the injured person either

- a) died of the injury without seeking the assistance of a doctor.
- b) first sought the assistance of a doctor for the injury, or
- c) first presented a claim to the Drug Liability Association²⁾ because of the injury.

(2) The total indemnity for injuries caused by the same substance in one or more drugs (serial injury) is moreover limited to NOK 100 million. When a serial injury has been ascertained, the King can decide which conditions for indemnity shall apply for continued sales of the substance causing the injury or of the drug³⁾ of which the substance forms part.

(3) The ceilings on the amounts do not apply to the costs of legal proceedings or to interest on claims for damages limited according to the present Chapter.

- 1) Cf. § 5 of Act no. 65 of 16 June 1989.
- 2) See § 3-2.
- 3) Cf. § 3-4.

§ 3-7. proportional settlement

(1) If the amounts in § 3-6 are not sufficient to indemnify all those entitled to damages, the amount of the damages shall be reduced proportionally. The total settlement must be approved in a ruling by the Oslo Probate Court. The Probate Act of 21 February 1930 applies correspondingly as appropriate to the ruling of the Probate Court, if nothing to the contrary is laid down in a regulation issued by the King.

(2) If there is reason to believe that a reduction may be necessary, the Drug Insurance scheme¹⁾ shall promptly give the Ministry²⁾ notice thereof in writing, and as soon as possible provide more detailed information concerning the amount and extent of the injuries. The Ministry²⁾ can in such an event take decisions concerning notice of claims, time limits, preliminary payments and the final settlement.

- 1) Cf. § 3-4.
- 2) The Ministry of Justice.

§ 3-8.1) personal liability and recourse

(1) A member of the Drug Liability Association²⁾ or a member's employee is only liable to the injured person for such compensation as is payable by the Drug Insurance scheme³⁾ according to the present Chapter. Chapter 2 nevertheless applies to losses which are not covered in consequence of the ceilings in § 3-6.

(2) The Drug Insurance scheme can claim recourse from a person who is obliged to take out insurance³⁾ who is not a member of the Drug Liability Association²⁾ and does not hold approved insurance, even though he is not personally liable to the injured person for the injury.

- 1) Amended by Act no. 113 of 27 November 1992 (see its

Chapter II, in force at the same time as the EEA Agreement (1 January 1994)).

- 2) Cf. § 3-5.
- 3) Cf. § 3-4.

§ 3-9. (miscellaneous provisions)

(1) The King can issue rules for the handling and settlement of disputes between an insurer, a policy-holder or an injured party, including for the establishment of a special drug injury board and of time limits for lawsuits following decisions by the board.

(2) A foreign producer who exports a drug¹⁾ to Norway must be represented by an agent with full powers to conduct legal proceedings and whose venue is at his place of business in the Realm. This does not apply when the importer has drug liability and is obliged to take out insurance in respect of the product in question according to § 3-4, cf. § 3-3.

- 1) See § 3-2.

§ 3-10.1) (position in relation to the Insurance Contracts Act)

(1) Where the relation between the Drug Insurance scheme²⁾ and members of the Drug Liability Association³⁾ is concerned, insurance according to § 3-4 is regarded as liability insurance, even if the member is not personally liable to the injured party for the injury.

(2) The provisions in part A (relating to non-life insurance) and part C (general provisions) of Act no. 69 of 16 June 1989 relating to Insurance Contracts apply to the Drug Insurance scheme if nothing to the contrary is provided in or in pursuance of the rules concerning drug liability in the present Act or appears from the context.

- 1) Amended by Act no. 69 of 16 June 1989.
- 2) Cf. § 3-4.
- 3) Cf. § 3-5.

§ 3-11.1) (limitation of claims under drug liability)

Claims for damages become statute-barred according to the rules in Act no. 18 of 18 May 1979 relating to the Limitation of Claims. However, the second, third and fourth paragraphs of § 9 do not apply. Instead a maximum time limit of 20 years applies from the date when the drug was supplied for consumption²⁾.

- 1) Added by Act no. 113 of 27 November 1992 (see its Chapter II, in force at the same time as the EEA Agreement (1 January 1994)).
- 2) See § 1-2 (2).

Chapter 4. Entry into force etc.

§ 4-1. Entry into force:

(1) The Act shall enter into force from such date¹⁾ as the King shall decide. Chapter 3 can be brought into force separately¹⁾ at another date than the rest of the Act.

(2) Chapters 1 and 2 of the Act will not apply to products which left the producer's control (cf. the third paragraph of § 1-2) before the entry into force of the Act. Chapter 3 of the Act will not apply to products supplied for consumption (cf. the second paragraph of § 1-2) before the entry into force of the Act.

- 1) The Act came into force on 1 January 1989 according to Royal Decree no. 1065 of 23 December 1988, except for Chapter 3 on special rules for drug liability, which was brought into force on 1 July 1989 according to Royal Decree no. 268 of 21 April 1989.

§ 4-2. Amendments to other Acts)

From the date when the present Act enters into force, Act no. 18 of 9 April 1976 relating to the rules for the choice of jurisdiction under international private law is repealed.¹⁾

- 1) See § 1-4.

Regulations

Ministry of Justice 1988-12-23 1065 Partial entry into force of Act no. 104 of 23 December 1988 relating to Product Liability. Delegation of authority.

§ 1-3 Ministry of Justice 1993-11-12 1028 Regulation concerning the suspension of the importer's liability according to the Product Liability Act for imports from states which have ratified the EEA Agreement and the Lugano Convention.