Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334)

ANNEX

RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS[1]

6. *Examples*

6.3. Sensitivity analysis

The factors used to calculate the risk of an injury scenario, namely the severity of the injury and the probability, often have to be estimated. This creates uncertainty. Probability in particular can be difficult to estimate, since the behaviour of consumers, for example, can be difficult to predict. Does a person perform a certain action often or only occasionally?

It is therefore important to consider the level of uncertainty of the two factors and to make a sensitivity analysis. The purpose of this analysis is to establish how much the risk level varies when the estimated factors vary. The example provided on the table below only shows the variation of probability, since the severity of the injury is usually predicted with more certainty.

A practical way of performing the sensitivity analysis is to repeat the risk assessment for a certain scenario, but to use a different probability for one or more steps in the scenario. For example, a candle containing seeds could cause a fire, because the seeds can catch fire and generate high flames. Furniture or curtains can catch fire and persons not in the room could inhale toxic fumes and suffer fatal poisoning:

Injury scenario	Injury type and location	Severity of injury	Probability of injury	Resulting probability	Risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are not in room, but inhale toxic fumes.	Fatal poisoning	4	— Seeds or beans catch fire: 90 % (0,9) — People not in the room for some time: 30 % (0,3) — Furniture or curtains catch fire: 50 % (0,5)	0 00675 > 1/1 000	Serious

			— (depends on surface on which candle is placed) Persons inhale toxic fumes: 5 % (0,05)	

The probability levels for the steps in the scenario were estimated as shown in the table.

The overall probability is 0,00675, which corresponds to > 1/1 000 in table 4. This leads to the conclusion of ‘serious risk’. Note that the exact probability is closer to 1/100 than to 1/1 000, which already gives some confidence in the risk level because it is a little deeper in the serious risk area of table 4 than the > 1/1 000 row suggests.

Suppose we are uncertain about the 5 % probability that persons inhale the toxic fumes. We could put it at a much lower 0,1 % (0 001 = 1 in a thousand). If we recalculate with that assumption, the overall probability is 0,000135, which translates into > 1/10 000. Nevertheless, the risk is still serious. Even if for some reason the probability were to be a factor of 10 lower, the risk would still be high. Therefore, although the probability may vary 10- or 100-fold, we still find a serious or high risk (the latter being quite close to ‘serious’). Thus, this sensitivity analysis lets us confidently assess the risk as serious.

In general, however, risk assessment should be based on ‘reasonable worst cases’: not too pessimistic on every factor, but certainly not too optimistic.

TABLE 1

Consumers

Consumers	**Description**
Very vulnerable consumers	Very young children: 0 to 36 months Others: Persons with extensive and complex disabilities
Vulnerable consumers	Young children: Children older than 36 months and younger than 8 years. Older children: Children 8 to 14 years Others: Persons with reduced physical, sensory or mental capabilities (e.g. partially disabled, elderly, including those over 65, with some reduction in their physical and mental capabilities), or lack of experience and knowledge
Other consumers	Consumers other than very vulnerable or vulnerable consumers

TABLE 2

Hazards, typical injury scenarios and typical injuries

Hazard group	Hazard(product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product and falls; or person bumps into product	Bruising; fracture, concussion
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child), or covers internal airway	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
	Possible to bite off small part from product	Person (child) swallows small part; the part gets stuck in the digestive tract	Digestive tract obstruction
	Sharp corner or point	Person bumps into sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture; blinding, foreign body in eye; hearing, foreign body in ear
	Sharp edge	Person touches sharp edge; this lacerates the skin or cuts through tissues	Laceration, cut; amputation
	Slippery surface	Person walks on surface, slips and falls	Bruising; fracture, concussion
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between parts	Person puts a limb or body in opening and finger, arm, neck, head, body or clothing is trapped;	Crushing, fracture, amputation, strangulation

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

		injury occurs due to gravity or movement	
Potential energy	Low mechanical stability	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; sprain; fracture, concussion; crushing; electric shock; burns
	Low mechanical strength	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; fracture, concussion; crushing; electric shock; burns
	High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture, concussion; crushing
	Elastic element or spring	Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	Bruising; dislocation; fracture, concussion; crushing
	Pressurised liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects	Dislocation; fracture, concussion; crushing; cuts (see also under fire and explosion)
Kinetic Energy	Moving product	Person in the line of movement of the	Bruising; sprain; fracture, concussion; crushing

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	product is hit by the product or run over	
Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)	Bruising; dislocation; fracture; crushing
Parts moving past one another	Person puts a body part between the moving parts while they move close by (scissor movement); the body part gets trapped between the moving parts and put under pressure (shearing)	Laceration, cut; amputation
Rotating parts	A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force	Bruising; fracture; laceration (skin of the head); strangulation
Rotating parts close to one another	A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part	Crushing, fracture, amputation, strangulation
Acceleration	Person on the accelerating product loses balance, has no support to hold on to and falls with some speed	Dislocation; fracture, concussion; crushing
Flying objects	Person is hit by the flying object and depending on the energy sustains injuries	Bruising; dislocation; fracture, concussion; crushing
Vibration	Person holding the product loses balance and falls; or prolonged contact	Bruising; dislocation; fracture; crushing

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		with vibrating product causes neurological disorders, osteoarticular disorder, trauma of the spine, vascular disorder	
	Noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Hearing injury
Electrical Energy	High/low voltage	Person touches part of the product that is at high voltage; the person receives an electric shock and may be electrocuted	Electric shock
	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam, etc., that hits a person	Burn, scald
	Live parts too close	Electric arc or sparks occur between the live parts. This may cause a fire and intense radiation	Eye injury; burn, scald
Extreme temperatures	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn, scald
	Hot surfaces	Person does not recognise the hot surface and touches it; the person sustains burns	Burn
	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on	Scald

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		the skin and causes scalds	
	Hot gases	Person breathes in the hot gases emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration	Burn
	Cold surfaces	Person does not recognise the cold surface and touches it; the person sustains frostbite	Burn
Radiation	Ultraviolet radiation, laser	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neurological disorders; eye injury; skin cancer, mutation
	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed	Neurological (brain) damage, leukaemia (children)
Fire and explosion	Flammable sub stances	Person is near the flammable substance; an ignition source sets the substance on fire; this causes injuries to the person	Burn
	Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
	Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire	Burn; poisoning
	Overheating	Product overheats; fire, explosion	Burn, scald; eye injury, foreign body

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			in eye; hearing injury, foreign body in ear
Toxicity	Toxic solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin	Acute poisoning; irritation, dermatitis
		Person breathes in solid or fluid, for example vomited material (pulmonary aspiration)	Acute poisoning in lungs (aspiration pneumonia); infection
	Toxic gas, vapour or dust	Person inhales substance from product; and/or substance gets on skin	Acute poisoning in lungs; irritation, dermatitis
	Sensitising substance	Person ingests substance from product, e.g. by putting it in mouth; and/or substance gets on skin; and/or person inhales gas, vapour or dust	Sensitisation; allergic reaction
	Irritating or corrosive solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; eye injury, foreign body in eye
	Irritating or corrosive gas or vapour	Person inhales substance from product, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes
	CMR substance	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets onto skin; and/	Cancer, mutation, reproductive toxicity

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		or person inhales substance as gas, vapour or dust	
Microbiological contamination	Microbiological contamination	Person gets into contact with contaminated product by ingestion, inhalation or skin contact	Infection, local or systemic
Product operating hazards	Unhealthy posture	Design causes unhealthy posture of person when operating the product	Strain; musculoskeletal disorder
	Overexertion	Design requires use of considerable force when operating the product	Sprain or strain; musculoskeletal disorder
	Anatomical unsuitability	Design is not adapted to human anatomy, which makes it difficult or impossible to operate	Sprain or strain
	Ignoring personal protection	Design makes it difficult for a person wearing protection to handle or operate the product	Various injuries
	Inadvertent (de)activation	Person can easily (de)activate product, which leads to unwanted operation	Various injuries
	Operational inadequacy	Design provokes faulty operation by a person; or product with a protective function does not provide expected protection	Various injuries
	Failure to stop	Person wants to stop the product, but it continues to operate in situation where this is unwanted	Various injuries
	Unexpected start	Product shuts down during a power	Various injuries

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	failure, but resumes operation in a hazardous way	
Inability to stop	In an emergency situation, person is not able to stop operation of the product	Various injuries
Inadequately fitting parts	Person tries to fit a part, needs too much force to fit, product breaks; or part is too loosely fitted and becomes loose during use	Sprain or strain; laceration, cut; bruising; entrapment
Missing or incorrectly fitted protection	Hazardous parts are reachable for a per son	Various injuries
Insufficient warning instructions, signs and symbols	User does not notice warning instructions signs and/or does not understand symbols	Various injuries
Insufficient warning signals	User does not see or hear warning signal (optical or audio), causing dangerous operation	Various injuries

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Table 3 **Severity of injury**

Introduction

These risk assessment guidelines distinguish between four levels of injury harm severity. It is important to realise that severity should be assessed completely objectively. The aim is to compare the severity of different scenarios and to set priorities, not to judge the acceptability of a single injury at this stage. Any injury harm that could easily have been avoided will be difficult to accept for a consumer. However, authorities can justifiably invest more effort into avoiding irreversible consequences than into preventing temporary discomfort.

In order to assess the severity of the consequences (acute injury or other damage to health), objective criteria can be found, on the one hand, in the level of medical intervention, and, on the other hand, in the consequences to the further functioning of the victim. Both could be expressed as cost, but the costs of consequences of health damage may be difficult to quantify.

Combining these criteria, the four levels may be defined as follows:

1. Harm or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.

2. Harm or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.

3. Harm or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.

4. Harm or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.

The following table, which should be considered as a guide rather than prescriptive or complete, provides examples of injuries at all four levels. National differences may exist, either cultural or caused by different systems of health care and financial arrangements. However, deviating from the proposed classification in the table will affect uniform assessment of risks in the EU; this should be clearly stated and explained in the risk assessment report, and reasons should be given.

Type of injury	**Severity of injury**			
	1	**2**	**3**	**4**
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm long on face) requiring stitches Tendon or into joint White of eye or cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/ dysfunction)
Bruising (abrasion/ contusion, swelling, oedema)	Superficial ≤ 25 cm^2 on face ≤ 50 cm^2 on body	Major > 25 cm^2 on face > 50 cm^2 on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion	—	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma
Entrapment/ pinching	Minor pinching	—	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.)	(Same outcome as for suffocation/ strangulation.)

Sprain, strain, musculoskeletal disorder	Extremities Joints Spine (no dislocation or fracture)	Knee ligaments strain	Ligament or tendon rupture/ tear Muscle tear Whiplash	—
Dislocation	—	Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth	Ankle Wrist Shoulder Hip Knee Spine	Spinal column
Fracture	—	Extremities (finger, toe, hand, foot) Wrist Arm Rib Sternum Nose Tooth Jaw Bones around eye	Ankle Leg (femur and lower leg) Hip Thigh Skull Spine (minor compression fracture) Jaw (severe) Larynx Multiple rib fractures Blood or air in chest	Neck Spinal column
Crushing	—	—	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis	Spinal cord Mid-low neck Chest (massive crushing) Brain stem
Amputation	—	—	Finger(s) Toe(s) Hand Foot (Part of) Arm Leg Eye	Both extremities
Piercing, puncturing	Limited depth, only skin involved	Deeper than skin Abdominal wall (no organ involvement)	Eye Internal organs Chest wall	Aorta Heart Bronchial tube Deep injuries in organs (liver,

				kidney, bowel, etc.)
Ingestion	—	—	Internal organ injury (Refer also to internal airway obstruction where the ingested object gets stuck high in the oesophagus.)	Permanent damage to internal organ
Internal air way obstruction	—	—	Oxygen flow to brain blocked without permanent consequences	Oxygen flow to brain blocked with permanent consequences
Suffocation/ Strangulation	—	—	Oxygen flow to brain blocked without permanent consequences	Fatal suffocation/ strangulation
Submersion/ Drowning	—	—	—	Fatal drowning
Burn/Scald (by heat, cold, or chemical substance)	1°, up to 100 % of body surface 2°, < 6 % of body surface	2°, 6-15 % of body surface	2°, 16-35 % of body surface, or 3°, up to 35 % of body surface Inhalation burn	2° or 3°, > 35 % of body surface Inhalation burn requiring respiratory assistance
Electric shock	(See also under burns as electric current can cause burns.)	Local effects (temporary cramp or muscle paralysis)	—	Electrocution
Neurological disorders	—	—	Triggered epileptic seizure	—
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing Complete loss of hearing (one ear)	Complete loss of hearing (both ears)

Poisoning from substances (ingestion, inhalation, dermal)	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Irreversible damage to nerve system Fatality
Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal)	Local slight irritation	Reversible eye damage Reversible systemic effects Inflammatory effects	Lungs, respiratory insufficiency, chemical pneumonia Irreversible systemic effects Partial loss of sight Corrosive effects	Lungs, requiring respiratory assistance Asphyxia
Allergic reaction or sensitisation	Mild or local allergic reaction	Allergic reaction, widespread allergic contact dermatitis	Strong sensitisation, provoking allergies to multiple substances	Anaphylactic reaction, shock Fatality
Long-term damage from contact with substances or from exposure to radiation	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Damage to nervous system, e.g. Organic Psycho Syndrome (OPS; also called Chronic Toxic Encephalopathy, also known as ‘painters' disease’). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nervous system	Cancer (leukaemia) Effects on reproduction Effects on offspring CNS depression

Microbiological infection		Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics-resistant organisms Fatality

TABLE 4

Risk level from the combination of the severity of injury and probability

Probability of damage during foreseeable lifetime of the product		**Severity of injury**			
		1	**2**	**3**	**4**
High	>50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S — Serious Risk

H — High risk

M — Medium risk

L — Low risk

Glossary of terms

Hazard : Source of danger involving the chance of being injured or harmed. A means of quantifying the hazard in a risk assessment is the severity of the possible injury or harm.

Product hazard : Hazard created by the properties of a product.

Risk : Balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time.

Risk assessment : Procedure for identifying and assessing hazards, consisting of three steps:

1. identification of the seriousness of a hazard;
2. determination of the probability that a consumer will be injured by that hazard;

		3. combination of the hazard with the probability.
Risk level	:	Degree of risk, which may be ‘serious’, ‘high’, ‘medium’ and ‘low’. When the (highest) level of risk has been identified, the risk assessment is complete.
Risk management	:	Follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk.

(**1**) If you need more information on the Risk Assessment method for harmonised products (both consumer and professional products) in relation to broader categories of public risks protected under EU harmonisation legislation, please refer to Part I, Chapter 5.3.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417, Division 6.3..