Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP, suspension for injection in prefilled syringe.
Influenza vaccine (split virion, inactivated).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:
A/Michigan/45/2015 (H1N1)pdm09 - like strain (A/Michigan/45/2015, NYMC X-275)
..... 15 micrograms HA**
A/Singapore/INFIMH-16-0019/2016 (H3N2) - like strain (A/Singapore/INFIMH-16-0019/2016, IVR-186)
..... 15 micrograms HA**
B/Colorado/06/2017 - like strain (B/Maryland/15/2016, NYMC BX-69A)
..... 15 micrograms HA**
Per 0.5 ml dose
* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2018/2019 season.
For the full list of excipients, see Section 6.1.
INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol- 9, which are used during the manufacturing process (see Section 4.3).

3 PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.
The vaccine, after shaking gently, is a slightly whitish and opalescent liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis of influenza.
INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP is indicated for the prevention of influenza disease for:
- active immunisation of adults, including pregnant women, and children from 6 months of age and older,
- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections 4.4, 4.6 and 5.1).

The use of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP should be based on official recommendations.

4.2 Posology and method of administration

Posology
Adults: 0.5 ml.
Paediatric population
Children from 36 months onwards: 0.5 ml.
Children from 6 months to 35 months of age: 0.25 ml. Clinical data are limited. See Section 6.6 for more information on administration of 0.25 ml dose.
If this is required by national recommendations, 0.5 ml may be given.
For children less than 9 years of age who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Infants less than 6 months of age: the safety and efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP administration (active immunisation) have not been established. No data are available.
Regarding passive protection: one 0.5ml dose given to pregnant women may protect infants from birth to less than 6 months of age; however, not all these infants will be protected (see section 5.1).

Method of administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection.
For adults and children from 36 months of age: the preferred site for intramuscular injection is the deltoid muscle.
For children from 12 to 35 months of age: the preferred site for intramuscular injection is the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate).
For children from 6 to 11 months of age: the preferred site for intramuscular injection is the anterolateral aspect of the thigh.

Precautions to be taken before handling or administering the medicinal product

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in Section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9.
Vaccination should be postponed in case of moderate or severe febrile disease or acute disease.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP should under no circumstances be administered intravascularly.
As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.
As with any vaccine, vaccination with INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP may not protect 100% of susceptible individuals.
Regarding passive protection, not all infants less than 6 months of age born to women vaccinated during pregnancy will be protected (see Section 5.1).
Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing
See Section 4.5.

4.5 Interaction with other medicinal products and other forms of interactions

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.
The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.
Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy
Pregnant women are at high risk of influenza complications, including premature labour and delivery, hospitalization, and death: pregnant women should receive an influenza vaccine.
INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP can be used in all stages of pregnancy. Larger datasets on safety of inactivated influenza vaccines are available for the second and third trimesters, compared with the first trimester; however data from worldwide use of inactivated influenza vaccines, including INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP, do not indicate any adverse foetal, and maternal outcomes attributable to the vaccine.

Data from four clinical studies with INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP administered in pregnant women during the second or third trimester (more than 5,000 exposed pregnancies and more than 5,000 live births followed up to approximately 6 months post-partum) did not indicate any adverse foetal, newborn, infant and maternal outcomes attributable to the vaccine.

In clinical studies conducted in South Africa and Nepal, there were no significant differences between the INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP and placebo groups with regards to foetal, newborn, infant and maternal outcomes (including miscarriage, stillbirth, premature birth, low birth weight).

In a study conducted in Mali, there were no significant differences between the INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP and control vaccine (quadrivalent meningococcal conjugate vaccine) groups with regards to prematurity rate, stillbirth rate and low birth weight/small for gestational age rate.

For additional information, see Sections 4.8 and 5.1.
Breastfeeding
INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP may be used during breastfeeding.
Fertility
No fertility data are available.

4.7 Effects on ability to drive and use machines

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile
In clinical trials approximately 10,300 individuals from 6 months of age received INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP.
Depending on immunization history and the age of the children, the dosage and the number of doses were different (see *Paediatric population* in subsection b. Tabulated list of adverse reactions).
Most of adverse reactions usually occurred within the first 3 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP, resolved spontaneously within 3 days after onset. The intensity of these reactions as mild to moderate.
The most frequently reported injection site reaction within 7 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP was injection site pain in all population.
The most frequently reported systemic reaction within 7 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP was headache in adults, elderly and children from 9 to 17 years of age,myalgia in children from 3 to 8 years of age, fever in children from 24 to 35 months of age and irritability in children from 6 to 23 months of age.

b. Tabulated list of adverse reactions
The data below summarize the frequencies of the adverse reactions that were recorded following vaccination with INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP during clinical trials and worldwide post-marketing experience.
Adverse events are ranked under headings of frequency using the following convention:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1,000 to <1/100);
Rare (≥1/10,000 to <1/1,000);
Very rare (<1/10,000),
Not known (cannot be estimated from available data).
Adult and elderly
The safety profile is based on data:
- from clinical trials in more than 5,000 adults and 4,400 elderly over 60 years of age,
- from worldwide post-marketing experience in the overall population (*).

ADVERSE REACTIONS	**FREQUENCY**
Blood and Lymphatic System Disorders	
Lymphadenopathy [(1)]	Uncommon
Transient thrombocytopenia	Not known*
Immune System Disorders	

Allergic reactions such as drug hypersensitivity [2], dermatitis atopic [2], urticaria [2, 5], oropharyngeal pain, asthma [1], rhinitis allergic [2], rhinorrhea [1], conjunctivis allergic [2]	Uncommon
Allergic reactions such as swelling face, pruritus [2, 5], erythema, rash, flushing [3], oral mucosal eruption [3], paraesthesia oral [3], throat irritation, dyspnea [2, 5], sneezing, nasal obstruction [2], upper respiratory tract congestion [2], ocular hyperaemia [2]	Rare
Allergic reactions such as rash erythematous, angioedema, shock	Not known*
Nervous System Disorders	
Headache	Very common
Dizziness [7], somnolence [7]	Uncommon
Hypoaesthesia [2], paresthesia	Rare
Neuralgia, convulsions, encephalomyelitis, neuritis, Guillain Barré Syndrome	Not known*
Vascular disorders	
Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases	Not known*
Gastrointestinal Disorders	
Diarrhea, nausea	Uncommon
Abdominal pain [2], vomiting	Rare
Skin and Subcutaneous System Disorders	
Hyperhidrosis [1]	Uncommon
Metabolism and Nutrition Disorders	
Decreased appetite	Rare
Musculoskeletal and Connective Tissue Disorders	
Myalgia	Very common
Arthralgia [1]	Uncommon
General Disorders and Administration Site Conditions	
Injection site pain, malaise [4]	Very common
Fever [6], shivering, injection site erythema, injection site induration, injection site swelling/oedema	Common
Asthenia [1], fatigue, injection site ecchymosis, injection site pruritus, injection site warmth [1], injection site discomfort	Uncommon
Flu-like symtoms [2],injection site exfoliation [3], injection site hypersensitivity [2]	Rare

[1] Rare in elderly [2] Reported during clinical trials in adults
[3] Reported during clinical trials in elderly [4] Common in elderly
[5] Not known in elderly [6] Uncommon in elderly
[7] Rare in adults

Paediatric population
Depending on immunization history, children from 6 months to 8 years of age received one or two doses of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP. Children/adolescents from 9 to 17 years of age received one dose.
Children from 6 to 35 months of age received the 0.25 ml formulation, and children from 3 years of age received the 0.5 ml formulation.

Children/adolescents from 3 to 17 years of age:
The safety profile is based on data:
- from clinical trials in 363 children from 3 to 8 years of age and in 296 children/adolescents from 9 to 17 years of age,
- from worldwide post-marketing experience in the overall population (*).

In children from 3 to 8 years of age, the most frequently reported reactions within 7 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP were injection site pain (59.1%), injection site erythema/redness (30.3%), myalgia (25.0%), malaise (22.3%) and injection site swelling/oedema (22.1%).
In children/adolescents from 9 to 17 years of age, the most frequently reported reactions within 7 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP were injection site pain (65.3%), headache (28.6%) and myalgia (27.6%).

ADVERSE REACTIONS	**FREQUENCY**
Blood and Lymphatic System Disorders	
Lymphadenopathy [1, 6]	Uncommon
Transient thrombocytopenia	Not known*
Immune System Disorders	
Allergic reactions such as urticaria, rash, pruritus [1, 6], oropharyngeal pain [1]	Uncommon
Allergic reactions such as rash erythematous, dyspnea, angioedema, shock	Not known*

Nervous System Disorders	
Headache	Very common
Dizziness [2]	Uncommon
Neuralgia, paresthesia, convulsions, encephalomyelitis, neuritis and Guillain Barré Syndrome	Not known*
Vascular disorders	
Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases	Not known*
Gastrointestinal Disorders	
Diarrhea [1], abdominal pain [1]	Uncommon
Musculoskeletal and Connective Tissue Disorders	
Myalgia	Very common
General Disorders and Administration Site Conditions	
Injection site pain, injection site erythema, injection site swelling/oedema, injection site induration [3], malaise, shivering [4]	Very common
Fever, injection site ecchymosis [5]	Common
Injection site pruritus, injection site warmth [2], injection site discomfort [2], crying [1], asthenia [2], fatigue	Uncommon

[1] Reported during clinical trials in children from 3 to 8 years old
[2] Reported during clinical trials in children/adolescents from 9 to 17 years old
[3] Common in children/adolescents from 9 to 17 years old
[4] Common in children from 3 to 8 years old
[5] Uncommon in children/adolescent from 9 to 17 years old
[6] Not known in children/adolescents from 9 to 17 years old

Children from6 to 35 months of age:
The safety profile is based on data:
- from clinical trials in 101 children from 6 to 35 months of age,
- from worldwide post-marketing experience in the overall population (*).
The most frequently reported reactions within 7 days following injection of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) were irritability (50.9%), injection site tenderness (36.6%), injection site erythema (34.0%), abnormal crying (34.0%), fever (29.0%) and appetite lost (28.3%).

ADVERSE REACTIONS	**FREQUENCY**
Blood and Lymphatic System Disorders	
Transient thrombocytopenia, lymphadenopathy	Not known*
Immune System Disorders	
Allergic reactions such as pruritus, rash erythematous, urticaria, dyspnea, angioedema, shock	Not known*
Metabolism and nutrition Disorders	
Appetite lost [1]	Very common
Psychiatric Disorders	
Crying abnormal [1], irritability [1]	Very common
Nervous System Disorders	
Headache [2], drowsiness [1]	Very common
Paresthesia, convulsions, encephalomyelitis	Not known*
Vascular disorders	
Vasculitis such as Henoch-Schonlein purpura, with transient renal involvement in certain cases	Not known*
Gastrointestinal Disorders	
Diarrhea, vomiting [1]	Common
Musculoskeletal and Connective Tissue Disorders	
Myalgia [2]	Very common
General Disorders and Administration Site Conditions	
Injection site tenderness, injection site erythema, , injection site induration, injection site ecchymosis, injection site swelling/oedema, fever	Very common
Shivering [2]	Common

[1] Reported in children from 6 to 23 months old
[2] Reported in children from 24 to 35 months old
c. Other special populations
Although only a limited number of subjects with co-morbidities were enrolled, studies conducted in renal transplant patients, asthmatic patients, or children from 6 months to 3 years of age with medical conditions being at especially high risk of developing serious flu-related complications showed no major differences in terms of safety profile of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP in these populations.
In clinical studies conducted in pregnant women in South Africa and Mali with INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP (see Sections 4.6 and 5.1), frequencies of local and systemic solicited reactions reported within 7 days following administration of the vaccine, were consistent with those reported for the adult population during clinical studies. In the South Africa study, local reactions were more frequent in the INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP group than in the placebo group in both HIV-negative and HIV-positive cohorts. There were no other significant differences in solicited reactions between INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP and placebo groups in both cohorts.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Cases of administration of more than the recommended dose (overdose) have been reported with INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP. When adverse reactions were reported, the information was consistent with the known safety profile of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP described in Section 4.8.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: influenza vaccine, ATC code: J07BB02
Immunogenicity
An antibody immune response is generally induced within 2 to 3 weeks. The duration of postvaccinal induced immunity varies but is usually 6-12 months.
Efficacy
Infants less than 6 months of age born to vaccinated pregnant women (passive protection)
Infants less than 6 months of age are at high risk of influenza, resulting in high rates of hospitalization; however influenza vaccines are not indicated for active immunisation in this age group.
Efficacy in infants of women who received a single 0.5 ml dose of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP during the second or third trimester of pregnancy has been demonstrated in clinical trials.
Efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP in infants following vaccination of pregnant women during the first trimester has not been studied in these trials. Necessary influenza vaccination during the first trimester should not be postponed (see section 4.6).
In randomized, controlled phase IV clinical studies conducted in Mali, Nepal and South Africa, approximately 5,000 pregnant women received INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP and approximately 5,000 pregnant women received placebo or control vaccine (quadrivalent meningococcal conjugate vaccine) during the second or third trimester of pregnancy. Vaccine efficacy against laboratory confirmed influenza in pregnant women was evaluated as a secondary endpoint in all three studies.
The studies conducted in Mali and South Africa demonstrated the efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy (see table 1). In the study conducted in Nepal, the efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy was not demonstrated.
Table 1: Influenza Attack Rates and INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP Efficacy against Laboratory-confirmed influenza in pregnant women

		Influenza Attack Rate (Any influenza A or B type) % (n/N)		**INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP Efficacy % (95% CI)**
		TIV	**Control***	
Mali		0.5 (11/2,108)	1.9 (40/2,085)	70.3 (42.2 to 85.8)

		TIV	**Placebo**	
South Africa		1.8 (19/1,062)	3.6 (38/1,054)	50.4 (14.5 to 71.2)

* Meningococcal vaccine
N: Number of pregnant women included in analysis
n: number of subjects with laboratory confirmed infuenza
CI: Confidence Interval

In the same randomized, controlled phase IV clinical studies conducted in Mali, Nepal and South Africa, 4530 of 4898 (92%) infants born to pregnant women who received INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP and 4532 of 4868 (93%) infants born to pregnant women who received a placebo or control vaccine (quadrivalent meningococcal conjugate vaccine) (see table 2) during the second or third trimester of pregnancy, were followed up until approximately 6 months of age.
The studies confirmed the efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP for prevention of influenza in infants from birth until approximately 6 months of age following vaccination of women during these trimesters of pregnancy. Women in their first trimester of pregnancy were not included in these studies; INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP efficacy in infants born to mothers vaccinated during the first trimester could therefore not be avaluated.
Table 2: Influenza Attack Rates and INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP Efficacy against Laboratory-confirmed influenza in infants following vaccination in pregnant women

		Influenza Attack Rate (Any influenza A or B type) % (n/N)		**INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP Efficacy % (95% CI)**
		TIV	**Control***	
Mali		2.4 (45/1,866)	3.8 (71/1,869)	37.3(7.6 to 57.8)
		TIV	**Placebo**	
Nepal		4.1 (74/1,820)	5.8 (105/1,826)	30.0 (5 to 48)
South Africa		1.9 (19/1,026)	3.6 (37/1,023)	48.8 (11.6 to 70.4)

* Meningococcal vaccine
N: Number of infants included in the analysis
n: number of subjects with laboratory-confirmed influenza
CI: Confidence Interval

The efficacy data indicate a waning protection of the infants born to vaccinated mothers by time after birth.
In the trial conducted in South Africa, vaccine efficacy was highest among infants 8 weeks of age or younger (85.8% [95% CI, 38.3 to 98.4]) and decreased over time; vaccine efficacy was 25.5% (95% CI, -67.9 to 67.8) for infants >8 to 16 weeks of age and 30.4% (95% CI, -154.9 to 82.6) for infants >16 to 24 weeks of age.
In the trial conducted in Mali, there is also a trend of higher efficacy of INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP in infants during the first 4 months after birth, with lower efficacy within the 5th month of surveillance and a marked fall within the 6th month where protection is no longer evident.

The prevention of influenza disease can only be expected if the infant(s) are exposed to strains included in the vaccine administered to the mother.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Buffer solution:

- Sodium chloride

- Potassium chloride
- Disodium phosphate dihydrate
- Potassium dihydrogen phosphate
- Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.5 ml of suspension in prefilled syringe (type I glass) with attached needle, equipped with a plunger stopper (elastomer chlorobromobutyl or chlorobutyl or bromobutyl) – pack size of 1, 10, 20 or 50.

0.5 ml of suspension in prefilled syringe (type I glass) without needle, equipped with a plunger stopper (elastomer chlorobromobutyl or chlorobutyl or bromobutyl) – pack size of 1, 10, 20 or 50.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.
The vaccine should not be used if foreign particles are present in the suspension.
Instructions for administration of 0.25 ml in children from 6 months to 35 months
When one dose of 0.25 ml is indicated, in order to eliminate half of the volume of the 0.5 ml syringe, the syringe should be held in an upright position and the plunger stopper should be pushed until it reaches the fine black line printed on the syringe. The remaining volume of 0.25 ml should be injected. See also Section 4.2.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi Pasteur14 Espace Henry Vallée69007 LyonsFrance

8 MARKETING AUTHORISATION NUMBER

PA2131/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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