### **Collection of National Surveillance Data and Assessments**

Member State: The Netherlands

Period: 2014-2017

#### **Introduction**

This report, gives an account of the Netherlands' fulfilment of its obligations under article 18, paragraph 6 of regulation 765/2008. For this report the template provided by the European Commission has been used. In this report the five Dutch MSAs are often mentioned using their (Dutch) abbreviation. These are:

- Netherlands Food and Consumer Product Safety Authority (NVWA)
- Human Environment and Transport Inspectorate (ILT)
- Radiocommunications Agency Netherlands (AT)
- Inspectorate SZW (iSZW)
- Health and youth Care Inspectorate (IGJ)

Please take into account that the national data systems of the MSAs are not designed for this specific data collection template, therefore not all fields could be filled. Missing data is therefore excluded from the report.

### **TEMPLATE Collection of National Surveillance Data and Assessments**

### <u>Section 1 - Information on resources available for and expenditures on</u> <u>market surveillance activities</u>

#### 1.A. Overview on general market surveillance activities

1 A.		2014	2015	2016	2017
1	Staff available to market surveillance authorities in FTE's, including inspectors	127,11	126,26	132,39	121,34
2	Total budget available to market surveillance activities in nominal terms (€) If not available, please provide an estimate of the total budget available	€14.404.605	€14.649.605	€15.018.350	€15.125.040

#### **1.B. Overview on sector specific market surveillance activities**

1 B.	31. Biocides	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	1,4	2,7	0,3	3,4
3	Expenditure laboratory tests (€) Number broken down into:	€ 33.000	€ 56.000	€ 34.000	€ 470.000
3.1	- expenditure in house testing (€)	€ 33.000	€ 56.000	€ 34.000	€ 470.000
4	Budget available to market surveillance activities (€)	€ 157.000	€ 298.000	€ 7.800	€ 17.600
	If not available, please provide an estimate of the budget available				
1 B.	22.Chemicals	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	13,8	16,7	11,4	12,7
3	Expenditure laboratory tests (€)	€ 557.000	€ 899.000	€ 413.000	€ 394.000
2.4	Number broken down into:	6 5 47 000	C 990 000	6 402 000	6 284 000
3.1 3.2	- expenditure in house testing (€)	€ 547.000	€ 889.000	€ 403.000	€ 384.000
4	<ul> <li>-expenditure external testing (€)</li> <li>Budget available to market surveillance activities (€)</li> </ul>	€10.000 € 600.000	€10.000 €655.000	€10.000 €450.000	€10.000 € 650.000
	If not available, please provide an estimate of the budget available				
1 B.	2. Cosmetics	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	16,1	11,0	18,2	14,1
3	Expenditure laboratory tests (€) Number broken down into:	€ 1.714.000	€ 902.000	€ 1.534.000	€ 1.080.000
3.1	- expenditure in house testing (€)	€ 1.714.000	€ 902.000	€ 1.534.000	€ 1.080.000
4	Budget available to market surveillance activities (€)	€ 514.000	€ 596.000	€ 970.000	€ 874.000
	If not available, please provide an estimate of the budget available				
1 B.	Electrical Appliances	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	6,1	7,5	10,1	4,7
3.1	- expenditure in house testing (€)	€ 347.000	€ 416.000	€ 642.000	€ 282.000
	Budget available to market surveillance	€ 476.000	€ 587.000	€ 735.000	€ 369.000

	activities (€)				
	If not available, please provide an estimate of the budget available				
1 B.	16. Appliances burning gaseous fuels	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	0,6	0,3	1,3	0,7
3	Expenditure laboratory tests (€)	€0	€0	€ 61.000	€ 11.000
	Number broken down into:				
3.1	- expenditure in house testing (€)	€0	€0	€ 61.000	€ 11.000
4	Budget available to market surveillance activities (€)	€ 75.000	€ 39.000	€ 115.000	€ 81.000
	If not available, please provide an estimate of the budget available				
1 B.	9. Machinery	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	12,4	7,3	6,8	7,2
2	Communication activities (% of total expenditure)	1%	1%	1%	1%
3	Expenditure laboratory tests (€)	€0	€0	€0	€0
	Number broken down into:				
3.1	- expenditure in house testing (€)	€0	€0	€0	€0
4	Budget available to market surveillance activities (€)	€1.764.000	€1.058.000	€985.500	€1.040.000
	If not available, please provide an estimate of the budget available				
1 B.	4. Personal Protective Equipment	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	1,4	3,9	4,2	5,6
2	Communication activities (% of total expenditure)	-	1%	1%	1%
3	Expenditure laboratory tests (€)	€ 8.000	€ 86.000	€3.200	€ 204.000
	Number broken down into:				
3.1	- expenditure in house testing (€)	€ 8.000	€ 86.000	€3.200	€ 204.000
4	Budget available to market surveillance activities (€)	€133.000	€471.000	€612.000	€597.000
	If not available, please provide an estimate of the budget available				
1 B.	30. GPSD	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	11,0	10,9	10,0	11,0

3	Expenditure laboratory tests (€)	€ 567.000	€ 561.000	€ 535.000	€ 621.000
	Number broken down into:				
3.1	- expenditure in house testing (€)	€ 567.000	€ 561.000	€ 535.000	€ 621.000
4	Budget available to market surveillance activities (€)	€ 998.000	€ 990.000	€ 896.000	€ 851.000
	If not available, please provide an estimate of the budget available				
1 B.	3. Toys	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	9,5	12,4	10,5	14,2
3	Expenditure laboratory tests (€)	€ 788.000	€	€	€ 1.410.
	Number broken down into:		1.106.000	1.043.000	000
3.1	- expenditure in house testing (€)	€ 788.000	€	€	€ 1.410.
			1.106.000	1.043.000	000
4	Budget available to market surveillance activities (€)	€ 503.000	€ 587.000	€ 408.000	€ 582.000
	If not available, please provide an estimate of the budget available				
1 B.	32. Textiles	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	3,2	2,4	1,6	1,4
3	Expenditure laboratory tests (€)	€ 335.000	€ 207.000	€ 139.000	€ 68.000
	Number broken down into:				
3.1	- expenditure in house testing (€)	€ 335.000	€ 207.000	€ 139.000	€ 68.000
4	Budget available to market surveillance activities (€)	€ 106.000	€ 117.000	€ 77.000	€ 116.000
	If not available, please provide an estimate of the budget available				
1 B.	23. Energy labelling	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	3,8	3,7	2,4	2,1
4	Budget available to market surveillance activities (€)	€ 304.000	€ 343.000	€ 224.000	€ 179.000
	If not available, please provide an estimate of				
	the budget available				
1 B.	the budget available17 Measuring instruments, Non-automaticweighing instruments, Pre-packagedproducts and Units of measurement.	2014	2015	2016	2017

2	Communication activities (% of total expenditure)	1	1	1	1
3	Expenditure laboratory tests (€)	30.000	0	0	0
	Number broken down into:				
3.1	- expenditure in house testing (€)	0	0	0	0
3.2	-expenditure external testing (€)	30.000	0	0	0
4	Budget available to market surveillance activities (€)	108.605	108.605	219.350	237.540
	If not available, please provide an estimate of the budget available				
1 B.	18. Electrical equipment under EMC	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	10,5	10,5	10,5	10,5
2	Communication activities (% of total expenditure)	2	2	2	2
3.2	-expenditure external testing (€)	1.500	1.500	0	0
4	Budget available to market surveillance activities (€)	50.000	50.000	50.000	50.000
	If not available, please provide an estimate of the budget available				
1 B.	19. Radio and telecom equipment under RTTE - RED	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	10,5	10,5	10,5	10,5
2	Communication activities (% of total expenditure)	2	2	2	5
3.2	-expenditure external testing (€)	90.700	1.500	0	0
4	Budget available to market surveillance activities (€)	50.000	50.000	50.000	50.000
	If not available, please provide an estimate of the budget available				
1 B.	7 Simple pressure vessels and Pressure equipment (PED)	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	0,2	0,3	0,5	0,5
4	Budget available to market surveillance activities (€)	29.000	43.500	72.500	72.500
	If not available, please provide an estimate of the budget available				
	40.15	2014	2015	2016	2017
1 B.	10 Lifts	2014	2015	2010	2017

4	Budget available to market surveillance activities (€)	€145.000	€145.000	€145.000	€145.000
	If not available, please provide an estimate of the budget available				
1 B.	13 Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres (AtEx)	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	0,2	0,3	1,0	1,0
4	Budget available to market surveillance activities (€)	€29.000	€43.500	€145.000	€145.000
	If not available, please provide an estimate of the budget available				
1 B.	5. Construction products	2014	2015	2016	2017
3.2	-expenditure external testing (€)	€18.000 (project smoke detectors)	0	0	0
1 B.	8. Transportable pressure equipment	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	0	0	0	0,5
1 B.	14. Pyrotechnics	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	6,5	5,5	4,7	4,7
3.2	-expenditure external testing (€)	120.000	120.000	130.000	140.000
1 B.	15. Explosives for civil uses	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	2,95	2,95	1,4	1,4
1 B.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly)	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	2	0,1	0,1	0,1
1 B.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly) AND 23. Eco-design and Energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	2014	2015	2016	2017
			+	+	1

				-	
3	Expenditure laboratory tests (€)	0	15.000	0	0
	Number broken down into:		(eco)		
3.1	- expenditure in house testing (€)	0	10.000 (eco)	0	0
3.2	-expenditure external testing (€)	0	2.500 (eco)	0	0
1 B.	24. Tyre labelling AND 27. Motor vehicles and tractors	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	3.2	3.2	3.2	1
1 B.	25. Recreational crafts	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	1	1.25	1.25	1.25
1 B.	26. Marine equipment	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	0	0	0	0.75
1 B.	1 Medical devices	2014	2015	2016	2017
1	Staff available in FTEs, including inspectors	31	29	31	31
3	Expenditure laboratory tests (€)	€0,-	€168.266	€ 74.240	€154.020
	Number broken down into:				
3.1	- expenditure in house testing (€)	€0,-	€168.266	€ 74.240	€154.020
3.2	-expenditure external testing (€)				
4	Budget available to market surveillance activities (€)	€ 3.301.000	€ 3.117.000	€ 3.270.000	€ 3.360.000
	If not available, please provide an estimate of the budget available				
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### Section 2 – Review of sector specific surveillance activities

#### 2.A. Inspections

2 A.	31. Biocides	2014	2015	2016	2017
1.	Total number of inspections broken down into:	91	152	5	11
1.1.	- number of reactive inspections	14	4	3	6
1.2.	- number of proactive inspections	77	148	2	5
3.	Total number of products tested in laboratories	10	26	10	158

2 A.	22.Chemicals	2014	2015	2016	2017
1.	Total number of inspections broken down into:	441	454	350	502
1.1.	- number of reactive inspections	158	174	117	130
1.2.	- number of proactive inspections	783	780	733	872
2.1.	- number of products inspected reactively	0	50	50	50
3.	Total number of products tested in laboratories	190	369	122	127
4.	Total number of products inspected in cooperation with the customs	0	0	0	1

2 A.	Electrical Appliances	2014	2015	2016	2017
1.	Total number of inspections broken down into:	309	331	445	236
1.1.	- number of reactive inspections	107	75	83	67
1.2.	- number of proactive inspections	202	256	362	169
3.	Total number of products tested in laboratories	177	212	203	107
4.	Total number of products inspected in cooperation with the customs	55	42	8	5

2 A.	16. Appliances burning gaseous fuels	2014	2015	2016	2017
1.	Total number of inspections broken down into:	52	25	69	51
1.1.	- number of reactive inspections	23	11	9	21
1.2.	- number of proactive inspections	29	14	60	30
3.	Total number of products tested in laboratories	0	0	19	4
4.	Total number of products inspected in cooperation with the customs	0	0	0	0

2 A.	9. Machinery	2014	2015	2016	2017
1.	Total number of inspections broken down into:	178	145	113	191
1.1.	- number of reactive inspections	19	34	50	90
1.2.	- number of proactive inspections	159	111	63	101
3.	Total number of products tested in laboratories	20	29	2	10
4.	Total number of products inspected in cooperation with the customs	20	29	2	2

2 A.	4. Personal Protective Equipment	2014	2015	2016	2017
1.	Total number of inspections broken down into:	59	53	45	73
1.1.	- number of reactive inspections	6	6	13	9
1.2.	- number of proactive inspections	53	47	32	64
3.	Total number of products tested in laboratories	3	35	1	68
4.	Total number of products inspected in cooperation with the customs	0	0	0	0

2 A.	30. GPSD	2014	2015	2016	2017
1.	Total number of inspections broken down into:	624	610	559	596
1.1.	- number of reactive inspections	35	31	14	34
1.2.	- number of proactive inspections	589	579	545	562
3.	Total number of products tested in laboratories	283	432	330	405
4.	Total number of products inspected in cooperation with the customs	75	77	3	46

2 A.	3. Toys	2014	2015	2016	2017
1.	Total number of inspections broken down into:	327	349	246	374
1.1.	- number of reactive inspections	132	114	40	79
1.2.	- number of proactive inspections	204	235	206	295
3.	Total number of products tested in laboratories	285	453	291	486
4.	Total number of products inspected in cooperation with the customs	110	107	65	253

2 A.	32. Textiles	2014	2015	2016	2017
1.	Total number of inspections broken down into:	71	70	48	74
1.1.	- number of reactive inspections	28	24	16	22
1.2.	- number of proactive inspections	43	46	32	52
3.	Total number of products tested in laboratories	53	60	43	30
4.	Total number of products inspected in cooperation with the customs	0	0	0	0

2 A.	23. Energy labelling	2014	2015	2016	2017
1.	Total number of inspections broken down into:	387	330	394	468
1.1.	- number of reactive inspections	3	1	4	0
1.2.	- number of proactive inspections	384	329	390	468

2 A.	2. Cosmetics	2014	2015	2016	2017
1.	Total number of inspections broken down into:	342	370	601	557
1.1.	- number of reactive inspections	132	150	179	174
1.2.	- number of proactive inspections	210	220	422	383
3.	Total number of products tested in laboratories	601	367	467	355

2 A.	17. Measuring instruments	2014	2015	2016	2017
1.	Total number of inspections broken down into:	25	60	0	53
1.1.	- number of reactive inspections	19	10	0	2
1.2.	- number of proactive inspections	6	50	0	51
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:	6	0	0	0
2.2.	- number of products inspected proactively	6	0	0	0
3.	Total number of products tested in laboratories	6	0	0	0

2 A.	18. Electrical equipment under EMC	2014	2015	2016	2017
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:	8	12	6	12
3.	Total number of products tested in laboratories	8	12	6	12

2 A.	19. Radio and telecom equipment under RTTE - RED	2014	2015	2016	2017
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:	250	162	153	145
3.	Total number of products tested in laboratories	166	160	152	145
4.	Total number of products inspected in cooperation with the customs	43	1	1	1

2 A.	7. Simple pressure vessels and Pressure equipment (PED)	2014	2015	2016	2017
1.1.	- number of reactive inspections		1	4	1

2 A.	10. Lifts	2014	2015	2016	2017
1.1.	- number of reactive inspections		18	20	14

2 A.	13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres (AtEx)	2014	2015	2016	2017
1.1.	- number of reactive inspections		1	1	1
1.2.	- number of proactive inspections				5

2 A.	8. Transportable pressure equipment	2014	2015	2016	2017
1.	Total number of inspections broken down into:				5
1.1.	- number of reactive inspections	0	0	0	4
1.2.	- number of proactive inspections	0	0	0	1
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:				5
2.1.	- number of products inspected reactively	0	0	0	4
2.2.	<ul> <li>number of products inspected proactively</li> </ul>				1

2 A.	11. Cableways	2014	2015	2016	2017
1.	Total number of inspections broken down into:	3	0	1	0
1.2.	- number of proactive inspections	1	1	1	1

2 A.	15. Explosives for civil uses	2014	2015	2016	2017
1.	Total number of inspections broken down into:	162	132	101	51
1.2.	- number of proactive inspections	162	132	101	51
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:	10	10	10	10
2.2.	- number of products inspected proactively	10	10	10	10

2 A.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly)	2014	2015	2016	2017
1.	Total number of inspections broken down into:	23 (packages)	0	0	0
1.1.	- number of reactive inspections	0	0	0	0
1.2.	- number of proactive inspections	23	0	0	0
2.	Total number of products inspected (incl. total number of products inspected in cooperation with the customs) broken down into:	17	0	0	0
2.2.	<ul> <li>number of products inspected proactively</li> </ul>	17			

2 A.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly) AND 23. Eco-design and Energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	2014	2015	2016	2017
1.	Total number of inspections broken down into:	152 81 (73 combi)	304	469	100
1.1.	- number of reactive inspections	0	0	0	3 for Eco design
1.2.	- number of proactive inspections				97
3.	Total number of products tested in laboratories	0	10 (Ecodesign)	0	0

2 A.	24. Tyre labelling AND 27. Motor vehicles and tractors	2014	2015	2016	2017
1.	Total number of inspections broken down into:	Tyre label: 293	Tyre label: 17	Tyre label: 0	Tyre label: 1
		Traffic Products: 1175	Traffic Products : 708	Traffic Products 795	Traffic Products : 9
1.1.	- number of reactive inspections	Tyre label: 293	Tyre label: 17	Tyre label: 0	Tyre label: 1
		Traffic Products : 1175	Traffic Products : 708	Traffic Products : 795	Traffic Products : 9

2 A.	25. Recreational crafts	2014	2015	2016	2017
1.	Total number of inspections broken down into:	305	172	133	90
1.1.	- number of reactive inspections	0	1	2	0
1.2.	- number of proactive inspections	305	71	131	90

2 A.	5. Construction products	2014	2015	2016	2017
1.	Total number of inspections broken down into:	511	484	289	60
1.1.	- number of reactive inspections	0	7	12	7
1.2.	- number of proactive inspections	511	477	277	53
3.	Total number of products tested in laboratories	3	0	0	0

2 A.	14. Pyrotechnics	2014	2015	2016	2017
1.	Total number of inspections broken down into:	295	275	300	306
1.2.	- number of proactive inspections	295	275	300	305
3.	Total number of products tested in laboratories	295	275	300	305
4.	Total number of products inspected in cooperation with the customs	10	10	5	0

2 A.	Medical devices	2014	2015	2016	2017
1.2.	- number of proactive inspections	119	197	189	130
	- desk inspections		3	90	109
	- reports		261	261	278
3.	Total number of products tested in laboratories	0	30	10	10

#### 2.B. Outcome of inspections

2 B.	31. Biocides	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	25	21	0	5
2.	Total number of non-compliant products found in cooperation with customs	5	5	5	5
2 B.	22.Chemicals	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States)	202	1075	80	224
	Number broken down into:				
2 B.	2. Cosmetics	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	100	74	141	148
2 B.	20. Electrical Appliances	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of	91	106	116	67
	measures by other Member States) Number broken down into:				
2.	Number broken down into: Total number of non-compliant products found in cooperation with	24	25	3	2
2. 2 B.	Number broken down into: Total number of non-compliant	24 2014	25 2015	3 2016	2 2017

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	products found in cooperation with customs				
2 B.	32. Textiles	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States)Number broken down into:	9	8	9	13
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
2 B.	23. Energy labelling	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	107	79	65	83
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
2 B.	17. Measuring instruments	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	13	9	0	0
1.1.	- number of products for which economic operators took corrective actions ("voluntary measures")	13	9	0	0
1.3.	- number of products for which other measures were taken, please specify:	0	0	0	0
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
3.	Total number of non-compliant products found following communication of measures by other Member States	0	0	0	0

2 B.	18. Electrical equipment under EMC	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	5	1	2	0
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
2 B.	19. Radio and telecom equipment under RTTE - RED	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States)Number broken down into:	178	143	138	125
2 B.	5. Construction products	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States)Number broken down into:	246	289	273	60
2 B.	8. Transportable pressure equipment	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:				1
1.1.	- number of products for which economic operators took corrective actions ("voluntary measures")				1
1.2.	- number of products for which market surveillance authorities took restrictive measures ("compulsory measures")				0

2.	Total number of non-compliant products found in cooperation with customs				0
3.	Total number of non-compliant products found following communication of measures by other Member States				0
2 B.	11. Cableways	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	0	0	0	0
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2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
3.	Total number of non-compliant products found following communication of measures by other Member States	0	0	0	0
2 B.	14. Pyrotechnics	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States)	198	195	256	260
	Number broken down into:				
1.2.	<ul> <li>number of products for which market surveillance authorities took restrictive measures ("compulsory measures")</li> </ul>	55	47	56	60
1.3.	- number of products for which other measures were taken, please specify:	55	47	56	60
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
3.	Total number of non-compliant products found following communication of measures by other Member States	0	0	0	0

1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	0	1	0	0
1.1.	- number of products for which economic operators took corrective actions ("voluntary measures")	0	1	0	0
1.2.	<ul> <li>number of products for which market surveillance authorities took restrictive measures ("compulsory measures")</li> </ul>	0	0	0	0
1.3.	- number of products for which other measures were taken, please specify:	0	0	0	0
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
3.	Total number of non-compliant products found following communication of measures by other Member States	0	0	0	0
2 B.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly)	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non-	0	0	0	0
	compliant products found in cooperation with customs and following communication of measures by other Member States)				
1.1.	cooperation with customs and following communication of	0	0	0	0
1.1.	<ul> <li>cooperation with customs and following communication of measures by other Member States)</li> <li>Number broken down into:         <ul> <li>number of products for which economic operators took corrective</li> </ul> </li> </ul>	0	0	0	0
	<ul> <li>cooperation with customs and following communication of measures by other Member States)</li> <li>Number broken down into:         <ul> <li>number of products for which economic operators took corrective actions ("voluntary measures")</li> <li>number of products for which market surveillance authorities took restrictive measures ("compulsory</li> </ul> </li> </ul>				

	communication of measures by other Member States				
2 B.	24. Tyre labelling AND 27. Motor vehicles and tractors	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	Tyre label: 0 Traffic products: 189	Tyre label: 0 Traffic products: 127	Tyre label: 0 Traffic products: 73	Tyre label: 0 Traffic products : 0
2.	Total number of non-compliant products found in cooperation with customs	0	0	0	0
3.	Total number of non-compliant products found following communication of measures by other Member States	0	0	0	0
2 B.	25. Recreational craft	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	91	44	33	60
2 B.	Medical devices	2014	2015	2016	2017
1.	Total number of non-compliant products found (incl. number of non- compliant products found in cooperation with customs and following communication of measures by other Member States) Number broken down into:	3	7	20	18

#### 2.C. Cross border cooperation

2 C.	Sectors: 31,22,20,16,9,4,30,3,32,23,2	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	Overall; less then 5	Overall less the 5.	Overall less then 5	Overall less then 5.
1.1.	<ul> <li>number of cases where the economic operator cooperated with authority</li> </ul>	0	0	0	0
1.2.	<ul> <li>number of cases where the economic operator did not cooperate and mutual assistance request was made to other authorities</li> </ul>	2	2	2	2
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	Less then 3	Less then 3	Less then 3	Less then 3
4.	Number of ADCO meetings and related subgroups in which national authorities participated	Overall ; around 10-12	Overall ; around 10-12	Overall ; around 10-12	Overall ; around 10-12
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	11 (Prosafe)	4	5	2
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	Sectors 4,7,9,10 en 13	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	Less then 5	Less then 5	5 - 10	5 - 10
1.1.	<ul> <li>number of cases where the economic operator cooperated with authority</li> </ul>	0-5	0-5	5-9	5-9
1.2.	<ul> <li>number of cases where the economic operator did not cooperate and mutual assistance request was made to other authorities</li> </ul>			1	1
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	Less then 3	Less then 3	3-5	3-5
3.1.	- RAPEX notification for serious risk			1	1
4.	Number of ADCO meetings and related subgroups in which national authorities participated	10	10	10	10
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project			1	1

2 C.	Sector 17	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	3	0	0
1.1.	<ul> <li>number of cases where the economic operator cooperated with authority</li> </ul>	0	3	0	0
1.2.	<ul> <li>number of cases where the economic operator did not cooperate and mutual assistance request was made to other authorities</li> </ul>	0	0	0	0
1.3.	- other, please specify	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	0	0	0	0
3.1.	- RAPEX notification for serious risk	0	0	0	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	0	0	0	0
3.3.	- Other, please specify	2	3	0	1
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2 & 2	2	2 & 2	2 & 2
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	1	1	2	2
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	Sectors: 18,19	2014	2015	2016	2017
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	13	2	8	30
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	1	0	1	1
3.1.	- RAPEX notification for serious risk	0	0	0	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	0	0	0	0
3.3.	- Other, please specify	1	0	1	1
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2 (ICSMS)	1 (ICSMS)	1 (ICSMS)	2 (ICSMS)
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	2	2	2	3

2 C.	Sector 5	2014	2015	2016	2017
x3.	<ul> <li>RAPEX notification for serious risk</li> </ul>	0	0	0	0
1.					
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	0	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2	2	2	2
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	1	1	0	1
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	Sector 8	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:				0
3.1.	- RAPEX notification for serious risk			1	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>				1
4.	Number of ADCO meetings and related subgroups in which national authorities participated		1	1	1
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project				0
6.	Number of officials participating in the European Commission exchange program				0

2 C.	Sector 11	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	0	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	0	1	1	0
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	0	0	0	0
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	Sector 14	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.1.	- RAPEX notification for serious risk	21	0	0	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	21	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2	2	2	2
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	1	1	1	3
6.	Number of officials participating in the European Commission exchange program	2	2	2	4

2 C.	15. Explosives for civil uses	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	1	0	0
1.1.	<ul> <li>number of cases where the economic operator cooperated with authority</li> </ul>	0	1	0	0
1.2.	<ul> <li>number of cases where the economic operator did not cooperate and mutual assistance request was made to other authorities</li> </ul>	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	0	0	0	0
3.1.	- RAPEX notification for serious risk	0	0	0	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	0	0	0	0
3.3.	- Other, please specify	0	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	0	1	1	1
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	0	0	0	0
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	21. Electrical and electronic equipment under RoHS and WEEE and batteries (partly)	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	0	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	0	1	0	0
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	0	0	0	0

2 C.	<b>21.</b> Electrical and electronic equipment under RoHS and WEEE and batteries (partly) AND 23. Eco-design and Energy labelling; efficiency requirements for hot-boilers fired with liquid or gaseous fuels	2014	2015	2016	2017
1.	Number of inspections during which the market surveillance authorities contacted the economic operator (manufacturer or EU importer) located in another Member State to obtain information or request voluntary corrective action across the EU. Number broken down into:	0	0	0	0
2.	Number of <i>mutual assistance requests received and fulfilled</i> by national authorities	0	0	0	0
3.	Number of <i>communications to other Member States</i> of measures against products non-compliant and/or presenting a risk made in accordance with:	0	0	0	0
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2(eco)	2(eco)	2(eco)	2(eco)
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	1	0	0	0

2 C.	24. Tyre labelling AND 27. Motor vehicles and tractors	2014	2015	2016	2017
4.	Number of ADCO meetings and related subgroups in which national authorities participated	0	0	1	2
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	0	0	0	0
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

2 C.	25. Recreational craft	2014	2015	2016	2017
3.1.	- RAPEX notification for serious risk	0	0	0	0
3.2.	<ul> <li>Notification of measures according to sectorial legislation or "Safeguard procedure"</li> </ul>	0	0	0	0
3.3.	- Other, please specify				
4.	Number of ADCO meetings and related subgroups in which national authorities participated	2	2	1	2
5.	Number of joint actions (i.e. projects partly financed by the European Commission) and other planned cooperation projects (such as regional cooperation projects) in which authorities participated. Please specify type and provide summary of project	0	1	0	0
6.	Number of officials participating in the European Commission exchange program	0	0	0	0

### <u>Section 3 – Member State evaluation of the functioning of market</u> <u>surveillance activities</u>

1. <u>The assessment of the coordination and cooperation mechanisms between national market</u> <u>surveillance authorities (Articles 17- 18 of Regulation (EC) 765/2008)</u>

# How effective has the cooperation and coordination among market surveillance authorities been in the relevant period?

Since 2008 a formal cooperation and coordination platform is in place for the five national product MSAs and Customs (National Alliance Group). Also the MSA for the enforcement of E-commerce legislation (Directive 2001/31) is participating since 2016 due to the growing importance of online sales. The Alliance group is tasked with the implementation of Directive 2008/765 by sharing information on strategies and best practices, comparing methods of enforcement, penalties and discussing problems encountered by the MSAs in their domains. The participation in Joint actions and developments and discussions in ADCOs are also on the agenda of the group. The group compares strategies on efficient market surveillance and enforcement such as inspection of quality systems of companies instead of product inspections. Since 2017 there is an (information) link with the National Inspectorate Council (CEO platform of all Inspectorates in the Netherlands). The Council is a national policy platform where Inspectorates share their insights on matters of strategy and long term visions. The Alliance Group has no decision powers as such and works on the bases of consensus.

Also on a more sectoral level there is cooperation, for example:

On a more operational level there are bilateral cooperation agreements between MSAs (REACH, Biocides, Chemical substances, Machines, PPE, LVD, RED, Pharmaceuticals, Cosmetics). In sector 17, 18 and 19 AT is actively participating in the relevant ADCOs (ADCO MI, EMC ADCO and ADCO RED). AT attends two to three meetings a year, participates in the organised Market Surveillance Campaigns and contributes to the group with proposals, presentations and exchange of knowledge and best practises. For sector 17 we expect an ADCO on Pre-packaged products, but this ADCO is out of scope of AT. The same goes for the NVWA and I-SZW in their sectors (Sectors 31, 20, 20, 16, 9, 4, 30, 3, 32, 23, 2, 4, 7, 9, 10, 13).

An example of a subject where cooperation on a national level takes place is the subject system inspections. In the domain of the NVWA there is an ongoing transition from product inspections to system inspections of companies. System inspections are felt to be more efficient when it comes to preventing the bringing on the market or distribution of large volumes of a broad spectrum of unsafe products. Also the ILT is moving towards more system inspections and is thereby cooperating with the NVWA. Experiences with these types of inspections are also discussed is the Alliance Group.

Another example is the Advisory Group on Status Determination that deals with the status determination of products located at interfaces between medical products (medicines and medical devices) and other product categories (for example: cosmetics, biocides, food supplements, commodities) and of which it is not immediately clear which legal provisions they have to comply with. In the advisory group, experts from the participating bodies IGJ, MEB, NVWA and CCMO have a seat, secretarial and substantive support comes from RIVM. The advisory group issues advice on the status of products to the participating authorities, who can then use that advice for supervision and enforcement. The advisory group has been formally endorsed by means of an agreement signed by the participating authorities on the 3<sup>rd</sup> of April 2018.

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

<u>Difficulties:</u> Not so much a problem, but worth mentioning is that the risk based approach of all the MSAs concerned not often results in the same priorities (risks/product groups/companies). This is mainly caused by the fact that there are a lot of differences between the product groups. So in practice there is less overlap in fields of interest and with that: less cause for operational cooperation then one would assume at first sight.

<u>Challenges:</u> There is a trend that products are simultaneously covered under multiple directives, e.g. cars (Automotive, RED). This demands more collaboration and coordination between MSAs if these directives are the responsibility of different MSAs. Dutch MSAs already work closely together when it comes to these types of products (for instance in the field of radio equipment with LVD safety issues) but since the number of these products increases a lot, this is and will be a challenging subject.

# 2. <u>The assessment of use and functioning of Rapid Alert System RAPEX (Art 12 GPSD and Art 22 of Regulation (EC) 765; and Art 11 of the GPSD / Art 23 of Regulation (EC) 765) at national level</u>

What was the coverage of the RAPEX system at national level (i.e. for which sectors do national market surveillance authorities generate RAPEX notifications and follow up (incl. reactions) to notifications received; for which sectors do they not; what are the means of circulation of the relevant information at national level)?

Rapex is used for:

NVWA; Sectors 31, 22, 20, 32, 3, 2, 16, 4, 9; AT: Sectors: 17, 18,19 iSZW sectors 4, 7, 9, 10, 13 ILT: 5, 14, 25 IGJ: not applicable

All information on RAPEX is coordinated by the national RAPEX contact point positioned within the NVWA. The contact point forwards notifications to other MSAs and also takes care of forwarding their notifications and reactions on notifications to the Commission and contact points of the other member states.

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

The integration of RAPEX into ICSMS makes the use of RAPEX more efficient. On a sectoral level it is worth mentioning that for construction products the AdCo PRR is developing their own risk assessment method because RAPEX is not sufficient to use.

There are still discrepancies between risk assessments by MSAs. Some notifications are seen as unfounded because of a lack of serious risk.

Have the RAPEX contact points and the relevant national procedures proven effective to ensure circulation of information to and from all authorities? Yes.

Have certain difficulties been encountered? Are there any aspects and/or procedures to improve? *No, there are no specific difficulties identified.* 

#### 3. <u>Assessment of use and functioning of the ICSMS information system (Art 23 of Regulation</u> (EC) 765) at national level

What is the coverage of the ICSMS system at national level (i.e. for which sectors do national market surveillance authorities already use ICSMS; for which sectors do they not, which types of inspections / are encoded in ICSMS by national market surveillance authorities)

Coverage NVWA sectors; 31,22, 20, 32, 3, 2, 16, 4, 9. Risk Based Product inspections i.e. Laboratory test results (non-conformity) on samples are encoded.

*Coverage iSZW sectors 4, 7, 9, 10, 13 ca 50% for cases that result in a non-conformity. In Joint Action Chainsaws (sector 9) ICSMS is used.* 

AT uses ICSMS for sectors 17, 18, 19 for all cases that result in a non-conformity. The intention for sector 17 is also to use ICSMS for all cases which are part of joint actions.

*Coverage ITL for the period 2014-2017 only reactive use for sectors: 5, 8, 11, 12, 14, 15, 21, 22, 23, 24, 25, 26, 27, 28, 31.* 

ICSMS is not applicable for IGJ.

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

The main problem addressed is that ICSMS competes with the own inspection data system of Dutch MSAs. Therefore inspectors have to fill in certain information twice: once in ICSMS and once in the national system. Another difficulty discovered is the lack of possibilities that ICSMS has concerning data analysis. ICSMS has only minimal possibilities for data analysis . ICSMS could be improved to generate data that can be easily used for data analysis. Solid data analysis is crucial for a risk based approach This is an important point, because it would generate extra benefits and incentives for member states to start using the system in full.

# Have the contact point and the relevant national procedures proven effective to ensure circulation of information to and from all authorities?

In general this can be confirmed also when it comes to introducing and making known the existence of ICSMS to all the MSAs. Dutch MSAs use a special mailbox for the information exchange with the MSAs. The contact information in ICSMS is useful for finding the right contact of the MSAs.

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

No, there are no specific difficulties identified.

#### 3.B. Assessment of the effectiveness of sector specific market surveillance activities

#### a. TARGETING: Is the targeting of products/economic operators to inspect deemed effective?

This could in general be confirmed. Practices differ per product group and MSA. Therefore, to give a better insight in the practices of Dutch MSAs the experiences of two of the Dutch MSAs (NVWA and IGJ) are described below:

#### <u>NVWA:</u>

Inspections are all risk based targeting product groups and companies that 1) most likely show noncompliance and 2) this non-compliance creates serious risks for consumers. The NVWA only has in theory about 250.000 physical inspection locations to cover (manufactures, importers, distributors) and another 45.000 web shops based in the Netherlands. The NVWA inspections target a list of around 1.000 companies (top of the distribution chain, large volumes, different relevant product groups, non-compliant behaviour) for product inspections (around 10 different product projects per annum). Another group of 200 major player companies has been selected for system inspections (audits) regarding their product safety focused quality systems. The NVWA assists selected companies to introduce or improve such a system in their daily operations Not every company is willing or capable to invest in such a system. Such companies will be subjected to product inspections only. In the period 2014-2017 around 18.000 product inspections were performed and 2200 system inspections which makes a grand total of 20.200 inspections for the NVWA.

Prioritization of product groups and target groups of companies is based on a risk analysis of the domains (sectors). The analysis is made using available data on three issues: 1. High non-conformity of product groups (for instance USB chargers, cots, cheap jewellery, tattoo ink, radio equipment, measuring instruments) leading to serious risks for the consumer/end user and known non-compliant behaviour of certain companies, 2. major product risks including those resulting from innovations., and 3. if relevant, data on fraud. Data input for these three fields comes from studies, former inspection results and experiences, RAPEX, ICSMS, complaints, incidents, injury registration, media and questions from parliament.

#### <u>IGJ:</u>

The inspectorate supervises all technologies that affect the entire field of care. These are medical devices, in vitro diagnostics, ionizing radiation and e-Health. Supervision objects are manufacturers of medical technology in the Netherlands and worldwide, notified bodies, resellers and authorized representatives. The aim is to promote the quality and safety of care.

The EU market is made up of approximately 500.000 medical devices and roughly 26.000 manufacturers. For the Netherlands this comes down to approximately 20.000 medical devices, 15.000 IVD's and around 1600 manufacturers. Given the market surveillance capacity available combined with the size of the national market the approach taken for supervision is risk based. Not only manufacturers of products are subject to inspections, the complete life cycle of products is also taken into account where the application of the products is supervised together with governance where applicable. Based on an annual risk management cycle product groups and critical steps in the product life cycle are identified and targeted for inspection. Results are considered and in many cases the subject is removed from the list in the next cycle. Dialogue with the different sectors has been

initiated to discuss approaches and possibilities to investigate the risk areas with as a final goal a sector defined and supported supervisory framework. An example of this is the Covenant Medical Technology defined and implemented in close cooperation with the Dutch hospitals. As a result of the European wide implants discussion the IGJ initiated the discussion about setting up a national registry for implants. In preparation for the new Medical Device Regulation (MDR) several sessions with the field have been organised discussing the changes and impact. For Post Market Surveillance (which is one of the major changes in the MDR) investigational inspections have been executed

As mentioned the national market surveillance agencies in the Netherlands are in general moving more and more towards company system inspections (measuring the compliance performance of large companies responsible for major volumes of different kinds of product groups with serious risks) and away from product inspections ("pin pricks"). Also more effort is put in empowering consumers/E- shoppers by giving them more information they can use when (or even better before) buying products. For example by publishing inspection results which in some sectors includes mentioning brand and type of the tested product or the web shop where the product was bought. This is done on the website of the NVWA. (<u>www.nvwa.nl</u>.)

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

The speed, volume and agility of the (online) market has become too high for traditional forms of market surveillance and demands a different approach in which getting stakeholders (consumers and businesses) more engaged in deterring non conformity is pivotal. For instance: The consumer can buy any product from a million and more web shops around the world. To suppose that MSAs can control these lines of direct supply to consumers is an illusion.

Also economic operators (on and offline) come and go in an ever faster pace. Enforcement procedures can take some time. In the meantime the economic operators can stop to exist and pop up under another (trade)name. These "hit and run" operators are very hard to tackle. Also non-compliant products will be taken from the market only to return within days under another name.

Although we believe that these new supply lines can certainly not be tackled by inspections alone we do think that more harmonized border controls can reduce the number of non-conformity. This means that there should be a shared focus of Customs on certain product groups and countries /regions/companies of origin. Also the inspection levels (pressure) should be more equal. For example Dutch customs has invested a lot of time and energy in inspecting shipments of cheap disposable gas lighters. The effect however on the availability of these lighters for Dutch consumers is disappointingly modest. This due to the fact that these lighters still find their way to Dutch retailers by other European ports of entry.

# **IMPLEMENTATION:** Are the targets set in the Market Surveillance Programme effectively implemented?

Yes. The planned actions are risk based projects. The surveillance methods that will be used within the framework of these actions are chosen for their expected results. These methods are the answers to the question what is needed ( communication, assisting, repression) to improve conformity in the specific situation. To be able to formulate these answers an analysis of the compliance behaviour of the economic operators involved is necessary; what is needed to change i.e. improve their behaviour. Such a so called target group analysis forms the base for successful actions and methods.

#### IMPACT OF EFFORTS: What effects had market surveillance action?

*This differs per product group and MSA. Therefore is this case the experiences of two Dutch MSAs (NVWA and AT) are described below:* 

As a rule economic operators (in The Netherlands) cooperate fully when a non-compliant product is detected during an inspection. This is done by taking measures in close contact with the NVWA aimed at removing the risk as soon as possible. These measures include withdrawing the product from the market and warning the public. From experience we know that the majority of noncompliancy is caused by the economic operator being unaware of the legal requirements. Contacts with the economic operators are aimed at informing and educating the (willing) economic operator in this field. Frequent offenders are put on a "black list" and confronted with more inspections and (cumulating) penalties until they change their behaviour The intervention policy the NVWA applies can be translated as: "Harsh where we must be harsh, soft where we can be soft". All depending on the behaviour of the economic operator. Companies with an adequate quality system are "rewarded" with less inspections. No products of them are taken as samples in product inspection projects. With these companies a relation of trust and transparency is maintained. Every year at least one evaluation meeting between the management of the company and the responsible account holder within the NVWA is held. AT has a similar approach as NVWA. AT works with intervention strategies where AT distinguishes different approaches on economic operators related to their willingness to cooperate with AT to put an end to formal non-compliance cases. AT does not have list of frequent offending economic operators in place. For digital market places a special approach is applied, they remove offers after a notification ("alert") from the NVWA in which the NVWA points out to the market place that the offered product or claim is non-compliant. With market places based in the Netherlands the NVWA is working on written agreements that will take the cooperation between these hosts and the NVWA to a higher level. Until now AT uses informal contacts to achieve collaboration with digital market places.

Consumer product related accidents are registered on a national level. It is however very difficult if not impossible to quantify the causality between unsafe products and injuries. This is due to the fact that many injuries occur as a result of the behaviour or even misconduct of the consumer. The exact chain of events resulting in the injury is often obscure in the registered data. Every year around 2.000 consumer complaints concerning products reach the NVWA. Many of them do not relate to the unsafety of the product but to the quality of the product or even the conditions of the contract between the consumer and the economic operator. There are no surveys on the satisfaction of businesses in relation to the activities of the NVWA. AT received several complaints concerning products that are falling under sector 17. In 2014: 127; 2015: 77; 2016: 52; 2017: 142. All of these complaints from consumers were related to products which were already in the market and could not be related to economic operators. Further, most complaints were unjustified.

#### Have certain difficulties been encountered? Are there any aspects and/or procedures to improve?

A well-known problem is that market surveillance authorities are in no position to check products when consumers buy them from web shops outside the EU and have them sent directly to their home address. More complicating is the development that more and more consumers are selling these goods to others on the internet from their home address. This is specifically done using market place platforms and also social media adding thousands of "mini companies" to the EU market. In this way lots of cheap products with possible serious non conformities are entering the EU market causing risks for consumers and other end users but also undermining bonafide enterprises with unfair competition. There is not a close collaboration with the authorities of third countries on bringing production standards to a higher level and stopping the export on products which are not in compliance with EU requirements. This is a point that could best be solved on the EU level.

The import and distribution of goods is for a fair share in hands of very small companies that are unaware of the existence of the (complex) EU product legislation or unable to grasp the meaning of this legislation. As mentioned the internet will probably contribute to more small enterprises that import goods from third countries without knowing anything about these products or the legislation that applies to them. This asks for an intensive educational approach which is however beyond the reach and capabilities of MSAs alone. It should be done by all stakeholders combined using their own specific strengths and preferably on an EU level.

# 3.C. Assessment of the effectiveness of cooperation between market surveillance and customs in a specific sector.

#### How effective was pooling expertise by market surveillance authorities and customs?

In the Netherlands there is in general a lot of cooperation between MSAs and customs. The intensity differs per product group and MSA. Some examples are given below:

The NVWA has a long standing working agreement with customs . Every year a list of priority products, countries of origin and - when possible - economic operators is concluded between customs and the NVWA. On the bases of digital loading bills customs informs the NVWA duly when a ship or plane carrying cargo that corresponds with the mentioned priority list is coming in. The NVWA then decides whether or not to inspect the goods in question. Around 400 inspections per annum are made. AT has special agreements made with customs to stop jammers enter the market (sector 18).

Have certain difficulties been encountered? Are there any aspects and/or procedures to improve and enhance the effectiveness of cooperation between MSAs and customs?

No, there are no specific difficulties identified.

#### What are the results and impact of cooperation with customs?

The risk based inspected number of products represent between 0,02 and 0,04 percent of the total of incoming goods. The number of non-compliant goods found vary depending on the product group in question (regions of 10 to 50 %).

Shipments of goods entering the market are inspected on a risk based approach (product group, country or region of origin, reputation of the company that imports the goods). Still a lot of shipments that answer to these criteria will not be inspected due to the high number of shipments entering the Netherlands through the port of Rotterdam related to the available workforce for inspection.

Also the information about these products (custom classification on the loading bills), is often not specific enough -or even misguiding- for MSAs recognize the shipment as one that answers to the mentioned criteria. As a result shipments can slip through. Also shipments are stopped on the basis of their classification for inspections without finding any relevant product.

# Have certain difficulties been encountered? Are there any aspects and/or procedures to improve and enhance the effectiveness of cooperation between MSAs and customs?

Included in answer above.

#### 3.D. Assessment of the effectiveness of cross-border surveillance in a specific sector

# Has cooperation with authorities and economic operators in other Member States allowed for improved cross-border market surveillance activities and enforcement?

International cooperation could be improved. In general the number of mutual assistance requests is very low. Also Dutch MSAs get very few communications of measures from other member states. Dutch MSAs do often participate in ADCOs and joint actions. More participation in ADCOs and Joint Actions is also one of the aims that was presented in the action plan in 2017 made by the alliance group mentioned before.

## Have certain difficulties been encountered? Are there any aspects and/or procedures to improve and enhance the effectiveness of cross-border surveillance?

Cross border surveillance is sometimes experienced as time consuming and inefficient. This differs however strongly per sector. There are sometimes problems finding the right MSA and person within that MSA to contact for an request. Also the language barrier plays a role and the different ways MSAs operates (methods and powers). Finally the risk assessment by MSAs sometimes differs.

### Annex 2 – Reference list of sectors

	Product sectors	Relevant legislation
1.	Medical devices (including In vitro	Directives 93/42/EEC, 98/79/EC and
	diagnostic medical devices and Active	90/385/EEC
	implantable medical devices)	
2.	Cosmetics	Regulation (EC) 1223/2009
3.	Τογs	Directive 2009/48/EC
4.	Personal protective equipment	Directive 89/686/EEC
5.	Construction products	Regulation (EU) 305/2011
6.	Aerosol dispensers	Directive 75/324/EEC,
7.	Simple pressure vessels and Pressure	Directives 2009/105/EC and 97/23/EC.
	equipment	Directives 2014/29/EU and 2014/68/EU
8.	Transportable pressure equipment	Directive 2010/35/EU
9.	Machinery	Directive 2006/42/EC
10.	Lifts	Directive 1995/16/EC - Directive
		2014/33/EU
11.	Cableways	Directive 2000/9/EC
12.	Noise emissions for outdoor	Directive 2000/14/EC
	equipment	
13.	Equipment and Protective Systems	Directive 1994/9/EC - Directive
	Intended for use in Potentially	2014/34/EU
	Explosive Atmospheres	
14.	Pyrotechnics	Directive 2007/23/EC - Directive
		2013/29/EU
15.	Explosives for civil uses	Directive 93/15/EEC - Directive
		2014/28/EU
16.	Appliances burning gaseous fuels	Directive 2009/142/EC
17.	Measuring instruments, Non-	Directives 2004/22/EC and 2009/23/EC -
	automatic weighing instruments, Pre-	Directives 2014/32/EU and 2014/31/EU;
	packaged products and Units of	Directive 2007/45/EC, 75/107/EEC and
	measurement	76/211/EEC; Directive 80/181/EEC
18.	Electrical equipment under EMC	Directive 2004/108/EC - Directive
		2014/30/EU
19.	Radio and telecom equipment under	Directive 1999/5/EC - Directive
	RTTE - RED	2014/53/EU
20.	Electrical appliances and equipment	Directive 2006/95/EC - Directive
	under LVD	2014/35/EU
21.	Electrical and electronic equipment	Directives 2011/65/EU, 2002/96/EC and
	under RoHS and WEEE and batteries	2006/66/EC
22.	Chemicals (Detergents, Paints,	Regulation (EC) 648/2004, Directive
	Persistent Organic Pollutants,	2004/42/EC, Regulation (EC) 850/2004,
	Fluorinated greenhouse gases, Ozone	Regulation (EC) 842/2006 and Regulation
	Depleting Substances, etc.)	(EU) 517/2014, Regulation (EC) 1005/2009
23.	Eco-design and Energy Labelling;	Directives 2009/125/EC and 2010/30/EU;
	Efficiency requirements for hot-boilers	Directive 1992/42/EEC

fired with liquid or gaseous fuels	
24. Tyre labelling	Regulation (EC) 1222/2009
25. Recreational craft	Directive 1994/25/EC - Directive
	2013/53/EU
26. Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
27. Motor vehicles and Tractors	Directive 2002/24/EC - Regulation (EU)
	168/2013; Directive 2007/46/EC; Directive
	2003/37/EC - Regulation (EU) 167/2013
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) 2003/2003
30. Other consumer products under GPSD	Directive 2001/95/EC
31. Biocides	Regulation (EU) 528/2012
32. Textile and Footwear labelling	Regulation (EC) 1007/2011 and Directive
	94/11/EC
33. Crystal glass	Directive 69/493/EEC
34 (Additional sectors – please specify)	