

# Market Surveillance Programme 2016

in accordance with Regulation (EC)  
No 765/2008 22/12/2015 V1.0





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# 1 Scope of application

Chapter 3 of Regulation (EC) No 765/2008<sup>1</sup> sets out the legal framework *for a Community system of market surveillance and for controls of products entering the Community market*.

The Market Surveillance Programme provides an overview of the measures taken for products that fall within the scope defined by Article 15 of said Regulation, which is worded as follows:

Article 15

## **Scope of application<sup>2</sup>**

Articles 16 to 26 shall apply to products covered by Community harmonisation legislation.

Each of the provisions of Articles 16 to 26 shall apply in so far as there are no specific provisions with the same objective in Community harmonisation legislation.

The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.

For the purposes of Articles 16 to 26, a 'product' shall mean a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.

Articles 27, 28 and 29 shall apply to all products covered by Community legislation in so far as other Community legislation does not contain specific provisions relating to the organisation of border controls.

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<sup>1</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

<sup>2</sup> Articles 16 to 26 contain the provisions on market surveillance, while Articles 27 to 29 contain those governing the controls of products entering the Community market.

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## 2 Purpose of market surveillance

The purpose of market surveillance is to ensure that products are put into circulation and use only if they pose no risk to personal health and safety and fulfil other requirements laid down in the relevant legal provisions. This serves not only to safeguard the interests of consumers, professional users and other persons but also to protect economic operators against unfair competition.

Market surveillance is about more than safe products, for many of the legal rules governing market surveillance are designed to afford other forms of protection. Examples are radio interference, efficient use of the radio spectrum, the precision of measuring instruments and the economical use of energy. Similarly, market surveillance is about more than consumer protection, because it also covers all products intended for use in an occupational environment.

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## **3 Competent authorities**

Depending on the legal provisions that apply to a given product, market surveillance is exercised either by federal or by provincial authorities.

It is also laid down in the Austrian Constitution that matters of federal administration are to be dealt with by default in the form of indirect federal administration; this involvement of the provinces in the exercise of federal executive powers is an element of the principle of federalism.

In the chapter headed Sectoral information, the competent authority is indicated for each product category.

### **3.1 Federal authorities**

The establishment of specific federal authorities (direct federal administration in constitutional parlance) is permissible only for the matters explicitly indicated in the Federal Constitution Act (Bundesverfassungsgesetz). In this case, executive powers are exercised by the specific federal authorities.

### **3.2 Authorities engaged in indirect federal administration**

Indirect federal administration means that the executive powers of the Federal Government are exercised in the provinces by the provincial governor and the provincial departments under his or her authority. In the first instance, they are exercised by the district commissions (Bezirkshauptmannschaften) or town councils (Magistrate) within the territory of the relevant administrative district. Supreme authority, however, remains in the hands of the competent federal minister, who may also issue orders to the provincial governor.

### **3.3 Authorities exercising powers belonging to the provinces**

The executive powers that belong to the provinces are exercised by the provincial government. In this case too, they are exercised in the first instance by the district commissions or town councils within the territory of the relevant

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administrative district.

For construction products for which the provinces are responsible, the Austrian Institute of Construction Engineering (Österreichisches Institut für Bautechnik – OIB) is entrusted by the provinces with the task of market surveillance as their central implementing agency.

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### 3.4 Addresses of district administrative authorities (Bezirksverwaltungsbehörden)

<b>Burgenland</b>	
Mayor of the City of Eisenstadt (Bürgermeister der Stadt Eisenstadt)	Rathaus Hauptplatz 35 7000 Eisenstadt, Austria Telephone: +43/26 82/705-0 Fax: +43/26 82/705-145 Email: rathaus@eisenstadt.at
Mayor of the City of Rust (Bürgermeister der Stadt Rust)	Rathaus Conradplatz 1 7071 Rust, Austria Telephone: +43/26 85/202-0 Fax: +43/26 85/202-12 Email: post@rust.bgld.gv.at
Eisenstadt (environs) District Commission (Bezirkshauptmannschaft Eisenstadt-Umgebung)	Ing. Julius Raab Strasse 1 7000 Eisenstadt, Austria Telephone: +43/57600/4188 Fax: +43/57600/4177 Email: bh.eisenstadt@bgld.gv.at
Güssing District Commission (Bezirkshauptmannschaft Güssing)	Hauptstraße 1 7540 Güssing, Austria Telephone: +43/57600/4691 Fax: +43/57600/4677 Email: bh.guessing@bgld.gv.at
Jennersdorf District Commission (Bezirkshauptmannschaft Jennersdorf)	Hauptplatz 15 8380 Jennersdorf, Austria Telephone: +43/57600/4700 Fax: +43/57600/4777 Email: bh.jennersdorf@bgld.gv.at
Mattersburg District Commission (Bezirkshauptmannschaft Mattersburg)	Marktgasse 2 7210 Mattersburg, Austria Telephone: +43/57600/4391 Fax: +43/57600/4377 Email: bh.mattersburg@bgld.gv.at
Neusiedl am See District Commission (Bezirkshauptmannschaft Neusiedl am See)	Eisenstädter Strasse 1a 7100 Neusiedl am See, Austria Telephone: +43/57600/4291 Fax: +43/57600/4277 Email: bh.neusiedl@bgld.gv.at
Oberpullendorf District Commission (Bezirkshauptmannschaft Oberpullendorf)	Hauptstraße 56 7350 Oberpullendorf, Austria Telephone: +43/57600/4491 Fax: +43/57600/4477 Email: bh.oberpullendorf@bgld.gv.at
Oberwart District Commission	Hauptplatz 1

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(Bezirkshauptmannschaft Oberwart)	7400 Oberwart, Austria Telephone: +43/57600/4591 Fax: +43/57600/4577 Email: bh.oberwart@bgld.gv.at
<b>Carinthia</b>	
Mayor of the City of Klagenfurt am Wörthersee (Bürgermeister der Stadt Klagenfurt am Wörthersee)	Rathaus Neuer Platz 1 9010 Klagenfurt am Wörthersee, Austria Telephone: +43/463/537-0 or -2201 Fax: +43/463/537-6110 Email: magistratsdirektion@klagenfurt.at
Mayor of the City of Villach (Bürgermeister der Stadt Villach)	Rathaus Rathausplatz 1 9500 Villach, Austria Telephone: +43/42 42/205-0 Fax: +43/42 42/205-1899 Email: magistratsdirektion@villach.at
Feldkirchen District Commission (Bezirkshauptmannschaft Feldkirchen)	Milesistrasse 10 9560 Feldkirchen, Austria Telephone: +43/50 536-67000 Fax: +43/50 536-67200 Email: post.bhfe@ktn.gv.at
Hermagor District Commission (Bezirkshauptmannschaft Hermagor)	Hauptstraße 44 9620 Hermagor, Austria Telephone: +43/50 536-63000 Fax: +43/50 536-63810 Email: post.bhhe@ktn.gv.at
Klagenfurt (rural) District Commission (Bezirkshauptmannschaft Klagenfurt-Land)	Völkermarkterring 19 9020 Klagenfurt am Wörthersee, Austria Telephone: +43/50 536-64000 Fax: +43/50 536-64001 Email: post.bhkl@ktn.gv.at
Sankt Veit an der Glan District Commission (Bezirkshauptmannschaft St. Veit an der Glan)	Hauptplatz 28 9300 St. Veit an der Glan, Austria Telephone: +43/50 536-68000 Fax: +43/50 536-68200 Email: post.bhsv@ktn.gv.at
Spittal an der Drau District Commission (Bezirkshauptmannschaft Spittal an der Drau)	Tiroler Strasse 16 9800 Spittal an der Drau, Austria Telephone: +43/50 536-62000 Fax: +43/50 536-62333 Email: post.bhsp@ktn.gv.at
Villach (rural) District Commission (Bezirkshauptmannschaft Villach-Land)	Verwaltungsdirektion Meister-Friedrich-Strasse 4 9500 Villach, Austria Telephone: +43/50 536-61000 Fax: +43/50 536-61341 Email: post.bhvl@ktn.gv.at
Völkermarkt District Commission (Bezirkshauptmannschaft Völkermarkt)	Spanheimergasse 2 9100 Völkermarkt, Austria Telephone: +43/50 536/65000 Fax: +43/50 536/65511 Email: post.bhvk@ktn.gv.at

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Wolfsberg District Commission (Bezirkshauptmannschaft Wolfsberg)	Am Weiher 5/6 9400 Wolfsberg, Austria Telephone: +43/50 536-66000 Fax: +43/50 536-66200 Email: post.bhwo@ktn.gv.at
<b>Lower Austria</b>	
Mayor of the City of Sankt Pölten (Bürgermeister der St. Pölten)	Rathaus Rathausplatz 3100 St. Pölten, Austria Telephone: +43/27 42/333-0 Fax: +43/27 42/333-1009 Email: magistratsdirektion@st-poelten.gv.at
Mayor of the City of Krems (Bürgermeister der Stadt Krems)	Rathaus Obere Landstrasse 4 3500 Krems an der Donau, Austria Telephone: +43/27 32/801-0 Fax: +43/27 32/801-269 Email: magdion@krems.gv.at
Mayor of the City of Waidhofen an der Ybbs (Bürgermeister der Stadt Waidhofen an der Ybbs)	Rathaus Oberer Stadtplatz 28 3340 Waidhofen an der Ybbs, Austria Telephone: +43/74 42/511-0 Fax: +43/74 42/511-99 Email: post@magistrat.waidhofen.at
Mayor of the City of Wiener Neustadt (Bürgermeister der Stadt Wiener Neustadt)	Hauptplatz 1 2700 Wiener Neustadt, Austria Telephone: +43/26 22/373-0 Fax: +43/26 22/373-323 Email: magistrat@wiener-neustadt.at
Amstetten District Commission (Bezirkshauptmannschaft Amstetten)	Preinsbacher Strasse 11 3300 Amstetten, Austria Telephone: +43/74 72/9025-0 Fax: +43/74 72/9025-21000 Email: post.bham@noel.gv.at
Baden District Commission (Bezirkshauptmannschaft Baden)	Schwartzstrasse 50 2500 Baden, Austria Telephone: +43/22 52/9025-0 Fax: +43/22 52/9025-22000 Email: post.bhbn@noel.gv.at
Bruck an der Leitha District Commission (Bezirkshauptmannschaft Bruck an der Leitha)	Fischamender Strasse 10 2460 Bruck an der Leitha, Austria Telephone: +43/21 62/9025-0 Fax: +43/21 62/9025-23000 Email: post.bhbl@noel.gv.at
Gänserndorf District Commission (Bezirkshauptmannschaft Gänserndorf)	Schönkirchner Strasse 1 2230 Gänserndorf, Austria Telephone: +43/22 82/9025-0 Fax: +43/22 82/9025-24000 Email: post.bhgf@noel.gv.at
Gmünd District Commission (Bezirkshauptmannschaft Gmünd)	Schremser Strasse 8 3950 Gmünd, Austria Telephone: +43/28 52/9025-0 Fax: +43/28 52/9025-25000 Email: post.bhgd@noel.gv.at

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Hollabrunn District Commission (Bezirkshauptmannschaft Hollabrunn)	Mühlgasse 24 2020 Hollabrunn, Austria Telephone: +43/29 52/9025-0 Fax: +43/29 52/9025-27000 Email: post.bhhl@noel.gv.at
Horn District Commission (Bezirkshauptmannschaft Horn)	Frauenhofner Strasse 2 3580 Horn, Austria Telephone: +43/29 82/9025-0 Fax: +43/29 82/9025-28000 Email: post.bhho@noel.gv.at
Korneuburg District Commission (Bezirkshauptmannschaft Korneuburg)	Bankmannring 5 2100 Korneuburg, Austria Telephone: +43/22 62/9025-0 Fax: +43/22 62/9025-29000 Email: post.bhko@noel.gv.at
Krems District Commission (Bezirkshauptmannschaft Krems)	Körnermarkt 1 3500 Krems an der Donau, Austria Telephone: +43/27 32/9025-0 Fax: +43/27 32/9025-30000 Email: post.bhkr@noel.gv.at
Lilienfeld District Commission (Bezirkshauptmannschaft Lilienfeld)	Am Anger 2 3180 Lilienfeld, Austria Telephone: +43/27 62/9025-0 Fax: +43/27 62/9025-31000 Email: post.bhlf@noel.gv.at
Melk District Commission (Bezirkshauptmannschaft Melk)	Abt Karl-Strasse 25a 3390 Melk, Austria Telephone: +43/27 52/9025-0 Fax: +43/27 52/9025-32000 Email: post.bhme@noel.gv.at
Mistelbach District Commission (Bezirkshauptmannschaft Mistelbach)	Hauptplatz 4-5 2130 Mistelbach, Austria Telephone: +43/25 72/9025-0 Fax: +43/25 72/9025-33000 Email: post.bhmi@noel.gv.at
Mödling District Commission (Bezirkshauptmannschaft Mödling)	Bahnstrasse 2 2340 Mödling, Austria Telephone: +43/22 36/9025-0 Fax: +43/22 36/9025-34000 Email: post.bhmd@noel.gv.at
Neunkirchen District Commission (Bezirkshauptmannschaft Neunkirchen)	Peischinger Strasse 17 2620 Neunkirchen, Austria Telephone: +43/26 35/9025-0 Fax: +43/26 35/9025-35000 Email: post.bhmk@noel.gv.at
Sankt Pölten District Commission (Bezirkshauptmannschaft St. Pölten)	Am Bischofteich 1 3100 St. Pölten, Austria Telephone: +43/27 42/9025-0 Fax: +43/27 42/9025-37000 Email: post.bhpl@noel.gv.at
Scheibbs District Commission (Bezirkshauptmannschaft Scheibbs)	Rathausplatz 5 3270 Scheibbs, Austria Telephone: +43/74 82/9025-0 Fax: +43/74 82/9025-38000 Email: post.bhsb@noel.gv.at

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Tulln (Bezirkshauptmannschaft Tulln)	District Commission	Hauptplatz 33 3430 Tulln, Austria Telephone: +43/22 72/9025-0 Fax: +43/22 72/9025-39000 Email: post.bhtu@noel.gv.at
Waidhofen an der Thaya (Bezirkshauptmannschaft Waidhofen an der Thaya)	District Commission	Aignerstrasse 1 3830 Waidhofen an der Thaya, Austria Telephone: +43/28 42/9025-0 Fax: +43/28 42/9025-40000 Email: post.bhwt@noel.gv.at
Wiener Neustadt (Bezirkshauptmannschaft Wiener Neustadt)	District Commission	Ungargasse 33 2700 Wiener Neustadt, Austria Telephone: +43/26 22/9025-0 Fax: +43/26 22/9025-41000 Email: post.bhwb@noel.gv.at
Vienna (environs) (Bezirkshauptmannschaft Wien-Umgebung)	District Commission	Leopoldstrasse 21 3400 Klosterneuburg, Austria Telephone: +43/2243/9025-0 Fax: +43/2243/9025-26000 Email: post.bhwu@noel.gv.at
Zwettl (Bezirkshauptmannschaft Zwettl)	District Commission	Am Statzenberg 1 3910 Zwettl, Austria Telephone: +43/28 22/9025-0 Fax: +43/28 22/9025-42000 Email: post.bhzt@noel.gv.at
<b>Upper Austria</b>		
Mayor of the City of Linz (Bürgermeister der Stadt Linz)		Altes Rathaus Hauptplatz 1 4041 Linz, Austria Telephone: +43/70/7070-0 Fax: +43/70/73 74 65 Email: info@mag.linz.at
Mayor of the town of Steyr (Bürgermeister der Stadt Steyr)		Rathaus Stadtplatz 27 4400 Steyr, Austria Telephone: +43/72 52/575-0 Fax: +43/72 52/575-385 Email: office@steyr.gv.at
Mayor of the City of Wels (Bürgermeister der Stadt Wels)		Rathaus Stadtplatz 1 4600 Wels, Austria Telephone: +43/72 42/235-0 Fax: +43/72 42/235-4740 Email: office@wels.at
Braunau am Inn (Bezirkshauptmannschaft Braunau am Inn)	District Commission	Hammersteinplatz 1 5280 Braunau am Inn, Austria Telephone: +43/77 22/803-0 Fax: +43/77 22/803-399 Email: bh-br.post@ooe.gv.at
Eferding (Bezirkshauptmannschaft Eferding)	District Commission	Stefan-Fadinger-Strasse 2-4 4070 Eferding, Austria Telephone: +43/72 72/24 07-0 Fax: +43/72 72/24 07-399 Email: bh-ef.post@ooe.gv.at

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Freistadt (Bezirkshauptmannschaft Freistadt)	District	Commission	Promenade 5 4240 Freistadt, Austria Telephone: +43/79 42/702-0 Fax: +43/79 42/702-399 Email: bh-fr.post@ooe.gv.at
Gmunden (Bezirkshauptmannschaft Gmunden)	District	Commission	Esplanade 10 4810 Gmunden, Austria Telephone: +43/76 12/792-0 Fax: +43/76 12/792-399 Email: bh-gm.post@ooe.gv.at
Grieskirchen (Bezirkshauptmannschaft Grieskirchen)	District	Commission	Manglbург 14 4710 Grieskirchen, Austria Telephone: +43/72 48/603-0 Fax: +43/732/7720-264399 Email: bh-gr.post@ooe.gv.at
Kirchdorf an der Krems (Bezirkshauptmannschaft Kirchdorf an der Krems)	District	Commission	Garnisonstrasse 1 4560 Kirchdorf/Krems, Austria Telephone: +43/75 82/685-0 Fax: +43/75 82/685-399 Email: bh-ki.post@ooe.gv.at
Linz (rural) (Bezirkshauptmannschaft Linz-Land)	District	Commission	Kärntnerstrasse 14-16 4020 Linz, Austria Telephone: +43/732/69414-0 Fax: +43/732/69414-66399 Email: bh-ll.post@ooe.gv.at
Perg (Bezirkshauptmannschaft Perg)	District	Commission	Dirnbergerstrasse 11 4320 Perg, Austria Telephone: +43/72 62/551-0 Fax: +43/72 62/551-399 Email: bh-pe.post@ooe.gv.at
Ried im Innkreis (Bezirkshauptmannschaft Ried im Innkreis)	District	Commission	Parkgasse 1 4910 Ried im Innkreis, Austria Telephone: +43/77 52/912-0 Fax: +43/77 52/912-399 Email: bh-ri.post@ooe.gv.at
Rohrbach (Bezirkshauptmannschaft Rohrbach)	District	Commission	Bahnhofstrasse 7-9 und 11 4150 Rohrbach, Austria Telephone: +43/72 89/8851-0 Fax: +43/72 89/8851-399 Email: bh-ro.post@ooe.gv.at
Schärding (Bezirkshauptmannschaft Schärding)	District	Commission	Ludwig Pfliegl-Gasse 11-13 4780 Schärding, Austria Telephone: +43/77 12/31 05-0 Fax: +43/77 12/31 05-399 Email: bh-sd.post@ooe.gv.at
Steyr (rural) (Bezirkshauptmannschaft Steyr-Land)	District	Commission	Spitalskystrasse 10a 4400 Steyr, Austria Telephone: +43/72 52/523 61-0 Fax: +43/72 52/523 61-399 Email: bh-se.post@ooe.gv.at
Urfahr (environs) (Bezirkshauptmannschaft Urfahr-Umgebung)	District	Commission	Peuerbachstrasse 26 4041 Linz, Austria Telephone: +43/732/73 13 01-0 Fax: +43/732/73 13 01-72399 Email: bh-uu.post@ooe.gv.at

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Vöcklabruck District Commission (Bezirkshauptmannschaft Vöcklabruck)	Sportplatzstrasse 1-3 4840 Vöcklabruck, Austria Telephone: +43/76 72/702-0 Fax: +43/76 72/702-399 Email: bh-vb.post@ooe.gv.at
Wels (rural) District Commission (Bezirkshauptmannschaft Wels-Land)	Herrengasse 8, Postfach 119 4602 Wels, Austria Telephone: +43/7242/618-0 Fax: +43/7242/618-399 Email: bh-wl.post@ooe.gv.at
<b>Salzburg</b>	
Mayor of the City of Salzburg (Bürgermeister der Stadt Salzburg)	Schloss Mirabell 5024 Salzburg, Austria Telephone: +43/662/8072-0 Fax: +43/662/8072-2085 Email: post@stadt-salzburg.at
Hallein District Commission (Bezirkshauptmannschaft Hallein)	Dr.-Adolf-Schärf-Platz 2 5400 Hallein, Austria Telephone: +43/62 45/796-0 Fax: +43/62 45/796-6019 Email: bh-hallein@salzburg.gv.at
Salzburg (environs) District Commission (Bezirkshauptmannschaft Salzburg-Umgebung)	Karl-Wurmb-Strasse 17 5020 Salzburg, Austria Telephone: +43/662/81 80-0 Fax: +43/662/81 80-5719 Email: bh-sl@salzburg.gv.at
Sankt Johann im Pongau District Commission (Bezirkshauptmannschaft St. Johann im Pongau)	Hauptstraße 1 5600 St. Johann/Pongau, Austria Telephone: +43/64 12/61 01-0 Fax: +43/64 12/61 01-6219 Email: bh-st-johann@salzburg.gv.at
Tamsweg District Commission (Bezirkshauptmannschaft Tamsweg)	Kapuzinerplatz 1 5580 Tamsweg, Austria Telephone: +43/64 74/65 41-0 Fax: +43/64 74/65 41-6519 Email: bh-tamsweg@salzburg.gv.at
Zell am See District Commission (Bezirkshauptmannschaft Zell am See)	Stadtplatz 1 5700 Zell am See, Austria Telephone: +43/65 42/760-0 Fax: +43/65 42/760-6719 Email: bh-zell@salzburg.gv.at
<b>Styria</b>	
Mayor of the City of Graz (Bürgermeister der Stadt Graz)	Rathaus Hauptplatz 8010 Graz, Austria Telephone: +43/316/872-0 Fax: +43/316/872-2369 Email: stadtverwaltung@stadt.graz.at
Graz (environs) District Commission (Bezirkshauptmannschaft Graz-Umgebung)	Bahnhofgürtel 85 8021 Graz, Austria Telephone: +43/316/70 75-0 Fax: +43/316/70 75-333 Email: bhgu@stmk.gv.at

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Bruck and Mürzzuschlag District Commission (Bezirkshauptmannschaft Bruck-Mürzzuschlag)	Dr.-Theodor-Körner-Strasse 34 8600 Bruck an der Mur, Austria Telephone: +43/38 62/899-0 Fax: +43/38 62/899-550 Email: bhbm@stmk.gv.at
Deutschlandsberg District Commission (Bezirkshauptmannschaft Deutschlandsberg)	Kirchengasse 12 8530 Deutschlandsberg, Austria Telephone: +43/34 62/2606-0 Fax: +43/34 62/2606-550 Email: bhdl@stmk.gv.at
Hartberg and Fürstenfeld District Commission (Bezirkshauptmannschaft Hartberg-Fürstenfeld)	Rochusplatz 2 8230 Hartberg, Austria Telephone: +43/33 32/606-0 Fax: +43/33 32/606-550 Email: bhhf@stmk.gv.at
Leibnitz District Commission (Bezirkshauptmannschaft Leibnitz)	Kadagasse 12 8430 Leibnitz, Austria Telephone: +43/34 52/829 11-0 Fax: +43/34 52/829 11-550 Email: bhlb@stmk.gv.at
Leoben District Commission (Bezirkshauptmannschaft Leoben)	Peter-Tunner-Strasse 6 8700 Leoben, Austria Telephone: +43/38 42/455 71-0 Fax: +43/38 42/47 775 Email: bhln@stmk.gv.at
Liezen District Commission (Bezirkshauptmannschaft Liezen)	Hauptplatz 12 8940 Liezen, Austria Telephone: +43/36 12/2801-0 Fax: +43/36 12/2801-550 Email: bhli@stmk.gv.at
Gröbming administrative offices of the Liezen District Commission (Politische Exposituren der Bezirkshauptmannschaft Liezen — PE Gröbming)	Hauptstraße 213 8962 Gröbming, Austria Telephone: +43/36 85/22136-0 Fax: +43/36 85/22136-550 Email: pegb@stmk.gv.at
Murau District Commission (Bezirkshauptmannschaft Murau)	Bahnhofviertel 7 8850 Murau, Austria Telephone: +43/35 32/2101-0 Fax: +43/35 32/2101-550 Email: bhmu@stmk.gv.at
Murtal District Commission (Bezirkshauptmannschaft Murtal)	Kapellenweg 11-13 8750 Judenburg, Austria Telephone: +43/35 72/832 01-0 Fax: +43/35 72/832 01-550 Email: bhmt@stmk.gv.at
South-East Styria District Commission (Bezirkshauptmannschaft Südoststeiermark)	Bismarckstrasse 11-13 8330 Feldbach, Austria Telephone: +43/31 52/25 11-0 Fax: +43/31 52/25 11-550 Email: bhso@stmk.gv.at
Voitsberg District Commission (Bezirkshauptmannschaft Voitsberg)	Schillerstrasse 10 8570 Voitsberg, Austria Telephone: +43/31 42/215 20-0 Fax: +43/31 42/215 20-550 Email: bhvo@stmk.gv.at

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Weiz (Bezirkshauptmannschaft Weiz)	District	Commissioner	Birkfelder Strasse 28 8160 Weiz, Austria Telephone: +43/31 72/600-0 Fax: +43/31 72/600-550 Email: bh.wz@stmk.gv.at
<b>Tyrol</b>			
Mayor of the City of Innsbruck (Bürgermeister der Stadt Innsbruck)			Rathaus Maria Theresien-Strasse 18 6010 Innsbruck, Austria Telephone: +43/512/53 60-0 Fax: +43/512/53 60-1766 Email: post.bezirks.gemeindeverwaltung@innsbruck.gv.at
Imst (Bezirkshauptmannschaft Imst)	District	Commissioner	Stadtplatz 1 6460 Imst, Austria Telephone: +43/54 12/69 96-0 Fax: +43/54 12/69 96-5215 Email: bh.imst@tirol.gv.at
Innsbruck (Bezirkshauptmannschaft Innsbruck)	District	Commissioner	Gilmstrasse 2 6020 Innsbruck, Austria Telephone: +43/512/53 44-0 Fax: +43/512/53 44-5005 Email: bh.innsbruck@tirol.gv.at
Kitzbühel (Bezirkshauptmannschaft Kitzbühel)	District	Commissioner	Hinterstadt 28 6370 Kitzbühel, Austria Telephone: +43/53 56/62131-0 Fax: +43/53 56/62131-6305 Email: bh.kitzbuehel@tirol.gv.at
Kufstein (Bezirkshauptmannschaft Kufstein)	District	Commissioner	Bozner Platz 1-2 6330 Kufstein, Austria Telephone: +43/53 72/606-0 Fax: +43/53 72/606-6005 Email: bh.kufstein@tirol.gv.at
Landeck (Bezirkshauptmannschaft Landeck)	District	Commissioner	Innstrasse 5 6500 Landeck, Austria Telephone: +43/54 42/69 96-0 Fax: +43/54 42/69 96-5415 Email: bh.landeck@tirol.gv.at
Lienz (Bezirkshauptmannschaft Lienz)	District	Commissioner	Dolomitenstrasse 3 9900 Lienz, Austria Telephone: +43/48 52/66 33-0 Fax: +43/48 52/66 33-6505 Email: bh.lienz@tirol.gv.at
Reutte (Bezirkshauptmannschaft Reutte)	District	Commissioner	Obermarkt 7 6600 Reutte, Austria Telephone: +43/56 72/6996-0 Fax: +43/56 72/6996-5605 Email: bh.reutte@tirol.gv.at
Schwaz (Bezirkshauptmannschaft Schwaz)	District	Commissioner	Franz-Josef-Strasse 25 6130 Schwaz, Austria Telephone: +43/52 42/69 31-5800 Fax: +43/52 42/69 31-5805 Email: bh.schwaz@tirol.gv.at

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<b>Vorarlberg</b>			
Bludenz	District	Commission	Schloss-Gayenhofplatz 2 6900 Bludenz, Austria Telephone: +43/55 52/61 36-0 Fax: +43/55 52/61 36-51095 Email: bhbludenz@vorarlberg.at
Bregenz	District	Commission	Seestrasse 1 6901 Bregenz, Austria Telephone: +43/55 74/49 51-0 Fax: +43/55 74/49 51-52095 Email: bhhbregenz@vorarlberg.at
Dornbirn	District	Commission	Klaudiastrasse 2 6850 Dornbirn, Austria Telephone: +43/55 72/308-0 Fax: +43/55 72/308-53095 Email: bhdornbirn@vorarlberg.at
Feldkirch	District	Commission	Schlossgraben 1 6800 Feldkirch, Austria Telephone: +43/55 22/35 91-0 Fax: +43/55 74/511-954095 Email: bhfeldkirch@vorarlberg.at
<b>Vienna</b>			
Municipal District Office, Vienna 1 District			Wipplingerstrasse 8 1010 Vienna Telephone: 4000-01000 Email: post@mba01.wien.gv.at
(Magistratisches Bezirksamt für den 1. Bezirk)			
Municipal District Office, Vienna 2 District			Karmelitergasse 9 1020 Vienna Tel.: Email: post@mba02.wien.gv.at
(Magistratisches Bezirksamt für den 2. Bezirk)			
Municipal District Office, Vienna 3 District			Karl-Borromäus-Platz 3 1030 Vienna Telephone: 4000-03000 Email: post@mba03.wien.gv.at
(Magistratisches Bezirksamt für den 3. Bezirk)			
Municipal District Office, Vienna 4 District			Rechte Wienzeile 105 1050 Vienna Telephone: 4000-04000 Email: post@mba04.wien.gv.at
(Magistratisches Bezirksamt für den 4. Bezirk)			
Municipal District Office, Vienna 5 District			Rechte Wienzeile 105 1050 Vienna Telephone: 4000-04000 Email: post@mba04.wien.gv.at
(Magistratisches Bezirksamt für den 5. Bezirk)			
Municipal District Office, Vienna 6 District			Hermannngasse 24-26 1070 Vienna Telephone: 4000-06000 Email: post@mba06.wien.gv.at
(Magistratisches Bezirksamt für den 6. Bezirk)			
Municipal District Office, Vienna 7 District			Hermannngasse 24-26 1070 Vienna Telephone: 4000-07000 Email: post@mba06.wien.gv.at
(Magistratisches Bezirksamt für den 7. Bezirk)			

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Municipal District Office, Vienna 8 District (Magistratisches Bezirksamt für den 8. Bezirk)	Wipplingerstrasse 8 1010 Vienna Telephone: 4000-08000 Email: post@mba01.wien.gv.at
Municipal District Office, Vienna 9 District (Magistratisches Bezirksamt für den 9. Bezirk)	Wilhelm-Exner-Gasse 5 1090 Vienna Telephone: 4000-09000 Email: post@mba09.wien.gv.at
Municipal District Office, Vienna 10 District (Magistratisches Bezirksamt für den 10. Bezirk)	Laxenburger Strasse 43-45 1100 Vienna Telephone: 4000-10000 Email: post@mba10.wien.gv.at
Municipal District Office, Vienna 11 District (Magistratisches Bezirksamt für den 11. Bezirk)	Enkplatz 2 1110 Vienna Telephone: 4000-11000 Email: post@mba11.wien.gv.at
Municipal District Office, Vienna 12 District (Magistratisches Bezirksamt für den 12. Bezirk)	Schönbrunner Strasse 259 1120 Vienna Telephone: 4000-12000 Email: post@mba12.wien.gv.at
Municipal District Office, Vienna 13 District (Magistratisches Bezirksamt für den 13. Bezirk)	Hietzinger Kai 1-3 1130 Vienna Telephone: 4000-13000 Email: post@mba13.wien.gv.at
Municipal District Office, Vienna 14 District (Magistratisches Bezirksamt für den 14. Bezirk)	Hietzinger Kai 1-3 1130 Vienna Telephone: 4000-13000 Email: post@mba13.wien.gv.at
Municipal District Office, Vienna 15 District (Magistratisches Bezirksamt für den 15. Bezirk)	Gasgasse 8-10 1150 Vienna Telephone: 4000-15000 Email: post@mba15.wien.gv.at
Municipal District Office, Vienna 16 District (Magistratisches Bezirksamt für den 16. Bezirk)	Richard-Wagner-Platz 19 1160 Vienna Telephone: 4000-16000 Email: post@mba16.wien.gv.at
Municipal District Office, Vienna 17 District (Magistratisches Bezirksamt für den 17. Bezirk)	Elterleinplatz 14 1170 Vienna Telephone: 4000-17000 Email: post@mba17.wien.gv.at
Municipal District Office, Vienna 18 District (Magistratisches Bezirksamt für den 18. Bezirk)	Martinstrasse 100 1180 Vienna Telephone: 4000-18000 Email: post@mba18.wien.gv.at
Municipal District Office, Vienna 19 District (Magistratisches Bezirksamt für den 19. Bezirk)	Gatterburggasse 14 1190 Vienna Telephone: 4000-19000 Email: post@mba19.wien.gv.at
Municipal District Office, Vienna 20 District (Magistratisches Bezirksamt für den 20. Bezirk)	Brigittaplatz 10 1200 Vienna Telephone: 4000-20000 Email: post@mba20.wien.gv.at

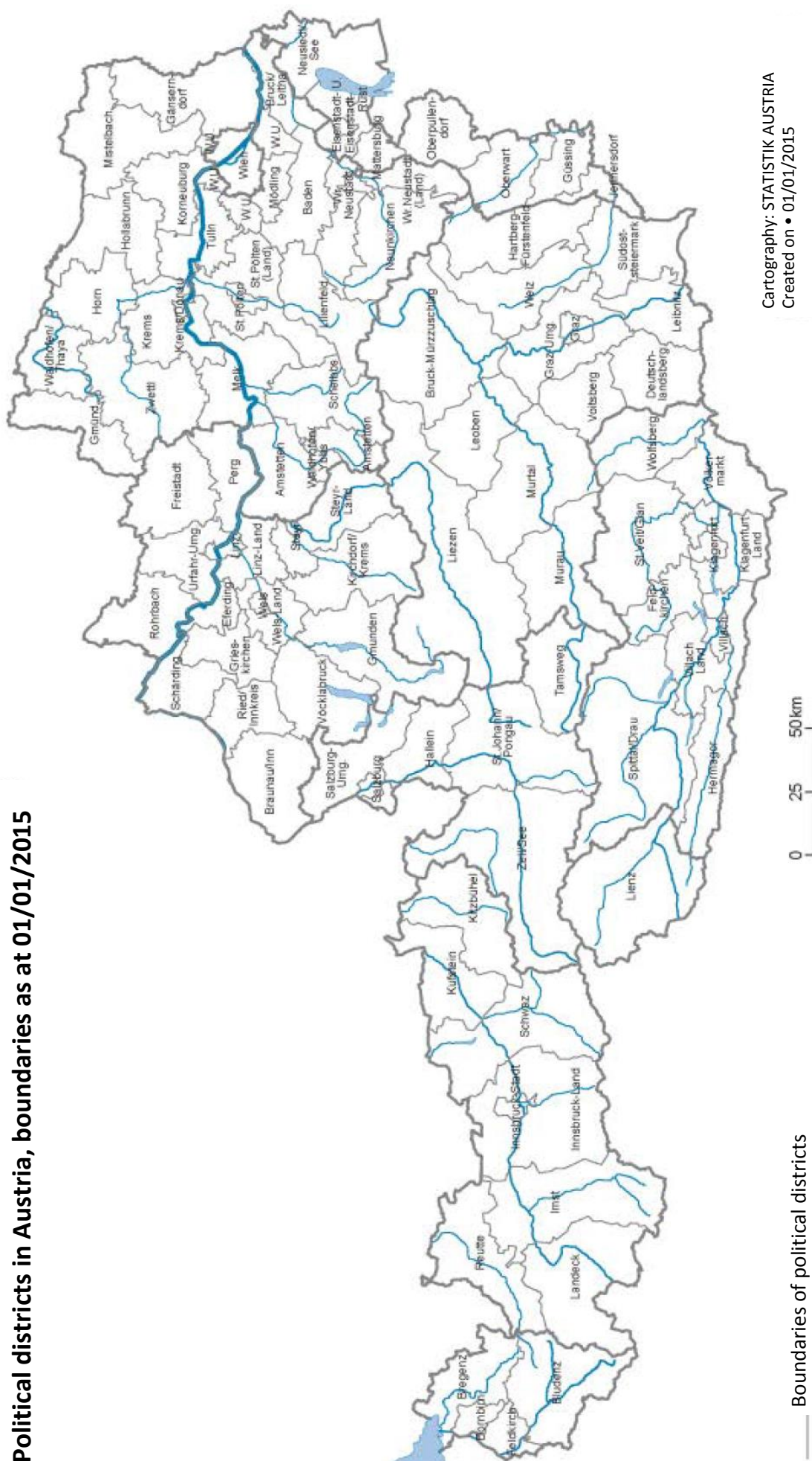
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Municipal District Office, Vienna 21 District (Magistratisches Bezirksamt für den 21. Bezirk)	Am Spitz 1 1210 Vienna Telephone: 4000-21000 Email: post@mba21.wien.gv.at
Municipal District Office, Vienna 22 District (Magistratisches Bezirksamt für den 22. Bezirk)	Schrödingerplatz 1 1220 Vienna Telephone: 4000-22000 Email: post@mba22.wien.gv.at
Municipal District Office, Vienna 23 District (Magistratisches Bezirksamt für den 23. Bezirk)	Perchtoldsdorfer Strasse 2 1230 Vienna Telephone: 4000-23000 Email: post@mba23.wien.gv.at

## Political districts in Austria, boundaries as at 01/01/2015



Cartography: STATISTIK AUSTRIA  
Created on • 01/01/2015

— Boundaries of political districts

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### 3.6 Addresses of the provincial government administrations (Ämter der Landesregierungen)

Office of the Provincial Government of Burgenland (Amt der Burgenländischen Landesregierung)	Landhaus Europaplatz 1 7000 Eisenstadt, Austria Telephone: 057/600 Fax: 057/61884 Email: post.lad@bgld.gv.at
Office of the Provincial Government of Carinthia (Amt der Kärntner Landesregierung)	Arnulfplatz 1 9020 Klagenfurt Telephone: 050/536 53000 Fax: 050/536 22980 Email: vpost@ktn.gv.at
Office of the Provincial Government of Lower Austria (Amt der Niederösterreichischen Landesregierung)	Landhausplatz 1 3100 St. Pölten, Austria Telephone: 02742/9005 Fax: 02742/9005 12060 Email: post.landnoe@noel.gv.at
Office of the Provincial Government of Upper Austria (Amt der Oberösterreichischen Landesregierung)	Klosterstrasse 7 4021 Linz, Austria Telephone: 0732/7720 Fax: 0732/7720 211668 Email: postst.post@ooe.gv.at
Office of the Provincial Government of Salzburg (Amt der Salzburger Landesregierung)	Chiemseehof 5010 Salzburg, Austria Telephone: 0662/8042 Fax: 0662/8042 2160 Email: post@salzburg.gv.at
Office of the Provincial Government of Styria (Amt der Steiermärkischen Landesregierung)	Burg 8011 Graz, Austria Telephone: 0316/877 Fax: 0316/877 3805 Email: post@stmk.gv.at
Office of the Provincial Government of Tyrol (Amt der Tiroler Landesregierung)	Eduard Wallnöfer-Platz 3 6020 Innsbruck, Austria Telephone: 0512/508 Fax: 0512/508 2185 Email: post@tirol.gv.at
Office of the Provincial Government of Vorarlberg (Amt der Vorarlberger Landesregierung)	Landhaus 6900 Bregenz, Austria Telephone: 05574/511 Fax: 05574/511 920195 Email: land@vorarlberg.at
Office of the Provincial Government of Vienna (Amt der Wiener Landesregierung)	Rathaus 1082 Vienna Telephone: 01/4000 Fax: 01/4000 9982120 (Chief Executive's Office (Magistratsdirektion)) Email: post@mda.magwien.gv.at

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## 4 Coordination of market surveillance authorities

Under Cabinet Decision 44/27 of 22 December 2009, the Federal Ministry of Science, Research and Economy (BMWFW) coordinates the Austrian market surveillance authorities pursuant to Regulation (EC) No 765/2008. This Decision, however, is without prejudice to the responsibility of the relevant competent department or province for the content of each part of the programme.

To this end, the contacts that already existed have been institutionalised, and a permanent Market Surveillance Coordination Body has been established. The body takes its decisions by consensus on the basis of a commitment on the part of all members to cooperation and active participation. It performs the following tasks:

### Tasks

- Acting as a communication forum and coordination body for the market surveillance authorities
- Coordinating cooperation between the market surveillance authorities and the customs administration
- Assisting the market surveillance authorities with a view to:
  - enhancing their effectiveness
  - helping them to meet their obligations under Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance
  - sharing experience and knowledge
  - formulating recommendations on market surveillance matters
- Coordinating the notification obligations under Regulation (EC) No 765/2008:
  - annual market surveillance plans
  - market surveillance authorities
  - contact addresses
  - quarterly progress reports
- Consulting business and consumer representatives on their priorities with regard to market surveillance

### Composition

- Representatives of the relevant organisations

### Members

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- Federal Ministry of Labour, Social Affairs and Consumer Protection (Bundesministerium für Arbeit, Soziales und Konsumentenschutz – BMASK)
- Federal Ministry of Finance – Customs Administration (Bundesministerium für Finanzen-Zollverwaltung)
- Federal Ministry of Health (Bundesministerium für Gesundheit)
- Federal Ministry of the Interior (Bundesministerium für Inneres – BMI)
- Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft – BMLFUW)
- Federal Ministry of Transport, Innovation and Technology (Bundesministerium für Verkehr, Innovation und Technologie – BMVIT)
- Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft – BMWFW)
- Federal Office of Metrology and Surveying (Bundesamt für Eich- und Vermessungswesen – BEV)
- Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen – BASG)/Agency for Health and Food Safety (Agentur für Gesundheit und Ernährungssicherheit – AGES), Medicines and Medical Devices Agency (PharmMed)
- Provincial Commissioners for Market Surveillance

## **Meetings**

- Twice yearly or as required



## **5 Cooperation with the customs authorities**

### **5.1 Organisation of the customs administration in Austria**

The Austrian Customs Service, as an integral part of the European customs system, works together with the customs administrations of the other Member States to ensure the safety and protection of the public in the EU but also to safeguard free movement of goods and fair competition for economic operators.

In Austria there are nine customs offices. The staff of each of these offices are based at, and operate at, several locations — units within the area of jurisdiction of the customs office. An up-to-date list of these locations may be retrieved from the following web page: <https://service.bmf.gv.at/Service/Anwend/Behoerden/start.asp?DisTyp=ZA>.

The personnel of the Customs Service are posted to the individual customs offices in line with regional requirements; they perform both internal and external duties, depending on their respective areas of activity. Each customs office has an internal structure with defined teams (organisational units) and operational specialisations. The number of the teams within a customs office varies according to the size of the office, but there are normally about 15 of them.

Within the customs office, a customer service team is responsible for an assigned group of customers, such as importing and exporting businesses, and a geographical area. Its task is to administer all customs and excise formalities for its customers within its assigned area, for example issuing licences and processing cases such as appeals or refund applications. A major element of the work of a customer service team is the customs clearance of goods being exported, imported or in transit on the premises of the Customs Service, including traveller clearance, and at authorised locations — places approved by the customs office for the clearance of goods, which are generally situated on the premises of carriers or other companies. There are no geographical restrictions on the authorisation of clearance locations, which means that customs clearance of goods outside the premises of customs offices may take place in any part of Austria.

### **5.2 Contact by market surveillance authorities with**

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## customs authorities

The point of contact for requests by market surveillance authorities for assistance from the customs authorities is the Federal Ministry of Finance

Division IV/8

Johannesgasse 5

1010 Vienna

Email: Post.VuB@bmf.gv.at

Telephone: (01) 51433 – 504 227

Telephone: (01) 51433 – 504 222

Telephone: (01) 51433 – 504 229.

Wherever possible, the following product information is to be provided:

1. CN code<sup>3</sup> or a detailed description of the goods which permits the identification of the CN code; this information is imperative, since products are declared in customs declarations with the CN code, and the selection of products for inspection can only be made on the basis of this code;
2. the country of origin;
3. the exporter or importer, particularly in cases where checks are meant to cover only specific economic operators;
4. information on characteristics of products which give grounds for the assumption that they may pose a serious risk to health, safety, the environment or other public interests within the meaning of Article 1 of Regulation (EC) No 765/2008;
5. information on the documentation prescribed by the Community harmonisation provisions for the marketing of the products or on labelling requirements imposed by such provisions;
6. information on the need for a 'CE' marking.

## 5.3 Contact by customers authorities with market surveillance authorities

The market surveillance authorities responsible for the individual product categories are listed in the next chapter. In the event of responsibilities differing from one place to another, as between district administrative authorities, the authority to be contacted would be the one in whose territory the customs

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<sup>3</sup> The Combined Nomenclature (CN) is an EC-wide uniform list of eight-digit product codes for external trade in the framework of the common commercial policy, particularly for the Common Customs Tariff and for statistical purposes. It was introduced by Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, as amended by Regulation (EU) No 861/2010. An online search for CN codes can be carried out at [http://ec.europa.eu/taxation\\_customs/dds2/taric](http://ec.europa.eu/taxation_customs/dds2/taric) (click on browse).

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authority is based.

Wherever possible, the following product information is to be provided:

1. Manufacturer
2. Type designation
3. Serial number, if available
4. Photo
5. EAN code
6. Importer
7. Grounds for suspicion

## 5.4 Further information

Further information on cooperation between customs and market surveillance authorities may be obtained from the European Commission publication *Guidelines for import controls in the area of product safety and compliance*, which is available at <https://www.bmf.gv.at/zoll/fuer-unternehmen/verbote-beschaenkungen/vub.html#Produktsicherheit>. In view of the guidelines drawn up by the Commission, the Federal Ministry of Finance revised the Procedural Guidelines for Product Safety (Arbeitsrichtlinie Produktsicherheit) (VB-0720) with effect from 1 February 2013. These Procedural Guidelines provide assistance with interpreting Regulation (EC) No 765/2008 with regard to the controls of products entering the Community market to be performed by customs authorities and customs bodies on the basis of this Regulation.

The Procedural Guidelines for Product Safety (VB-0720) were published in the financial documentation system (Findok). Findok can be accessed on the website of the BMF ([www.bmf.gv.at](http://www.bmf.gv.at)) or directly via the following link: <https://findok.bmf.gv.at/findok/welcome.do>. The current version of the Procedural Guidelines for Product Safety (VB-0720) can be accessed via the following link: <https://findok.bmf.gv.at/findok/link?titel=vb-0720&fassung=aktuell&bereich=rl>.

## 6 Sectoral information

This chapter contains details of the planned market surveillance measures in individual product categories, which are listed in alphabetical order of their German designations.

### EU legal provisions

These are Community harmonisation rules which, under Regulation (EC) No 765/2008, must be taken into account for the product category in question.

### Transposition in Austria

In many instances, the EU has enacted Directives, which need to be transposed into national law before they can be applied to legal subjects. In the case of EU Regulations, which are directly applicable, national transposition is not required.

### Competent federal authority

The competent federal authority is the highest decision-making body and the point of contact for intergovernmental consultation.

### Market surveillance authority

This is the executive authority of first instance. In areas of federal competence, this is a federal authority; where the provinces administer matters on behalf of the Federal Government or exercise their own powers, market surveillance is exercised in the first instance by the relevant district administrative authority.

### Basic strategy

Market surveillance may be either proactive or reactive. Proactive market surveillance is carried out on the basis of longer-term plans, involving the selection of product groups on the basis of inherent product-related risk or of information indicating that a problem might exist.

Not all market surveillance measures, however, can be planned in advance, since market surveillance authorities have to respond immediately to events such as accidents, notifications or user complaints. Such measures are described as

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'reactive market surveillance'.

### **Criteria for the selection of products**

Products are selected for review in the light of circumstances in the relevant sector. The applicable criteria are enumerated in this chapter.

### **Cooperation with other authorities**

In the European internal market, great importance is attached to both European cooperation and national coordination with other authorities. This chapter contains details of these activities.

### **Where surveillance takes place**

Surveillance can take place, for example, in retail outlets, in wholesalers' premises, in production facilities, in importers' premises, at exhibitions, during customs clearance or even in the context of distance selling.

### **Forms of surveillance**

Surveillance may, for instance, entail checking inscriptions, documentation and other administrative requirements by perusal, laboratory examination or inspections on the manufacturer's or importer's premises.

### **Product groups scheduled for surveillance**

This item contains a list of the product groups that are to be priority targets of official surveillance during the period of the surveillance programme.

## **6.1 Active implantable medical devices**

EU legal provisions	Directive 90/385/EEC on active implantable medical devices
Transposition in Austria	Medical Devices Act – MPG, BGBl. No 657/1996 as amended
Competent federal authority	Federal Ministry of Health (Bundesministerium für Gesundheit) Division III/3 Radetzkystrasse 2, 1030 Vienna, Austria Tel. +43-1/711 00-4602

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Market surveillance authority	Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen) Traisengasse 5, 1200 Vienna, Austria Tel.
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## Basic strategy

Risk-based system.

Market surveillance by the Federal Office for Safety in Health Care (BASG) comprises both reactive and proactive surveillance.

### 1. Reactive market surveillance

#### Systematic vigilance

Reactive market surveillance is based on a statutory notification requirement. Under Section 70(1) and (3) of the Medical Devices Act, all serious incidents are to be reported to the BASG without delay as soon as a causal link is established between a malfunction or failure of a medical device and the occurrence of the incident. If this link is not evident, the manufacturer must investigate the existence of such a link and report its findings to the BASG within ten days.

#### Remedial measures in the field

If the analysis of the cause of the incident reported to the BASG reveals a new systemic problem that poses an unreasonable risk to the Austrian and European markets, a remedial measure is taken in the field in Austria, that is to say the recall of the devices or batch in question or the communication of safety information to all users of the devices, in order to reduce any risk to patients, users or third parties. Under Section 77(2) of the Medical Devices Act, the BASG informs the other Member States of these remedial measures in the framework of a National Competent Authority Report (NCAR) with a view to ensuring that these measures are implemented throughout the European Economic Area.

If the BASG is informed by Austrian manufacturers of the initiation of a remedial measure which is not attributable to a specific incident, the EU Member States are informed in this case too by means of an NCAR in accordance with Section 77(2) of the Medical Devices Act.

#### Certificates of free sale

When applications are made for the issue of a certificate of free sale, the definition and classification of the device, as well as its marking, are checked for

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compliance with the statutory requirements.

## **2. Proactive market surveillance**

### Surveillance cases

In these cases, the focus is primarily on verifying that devices are properly defined and classified and bear the proper markings.

### Inspections:

In addition, an inspection is conducted to verify in the field the findings set out in the exposition of the facts.

## **Safety alerts and safety information**

### 1. Safety alerts

Safety alerts are warnings about a clear and present danger to the life and limb of a patient, user or third party arising from the malfunctioning of a medical device. In order to reduce such a specific risk, a safety alert is drawn up by the BASG. This is published on the BASG website and, with due regard to the inherent risks within the market, is publicised, typically by being sent to the provincial health boards for distribution to hospitals and doctors' surgeries.

### 2. Safety information

Safety information is information material which draws attention to a general risk and is not normally restricted to a specific device on the Austrian market. This risk can normally be mitigated by exercising particular care, observing specific precautions or the like. The need to respond to safety information is typically somewhat less urgent. It is also disseminated by means of publication on the BASG website and — depending on the level of urgency and the diffusion of the relevant devices — by means of e-mails.

## **Systematic vigilance with regard to medical devices**

Serious incidents involving medical devices as well as near misses must be reported to the competent authority. Even the possibility that a medical device was partly to blame for a serious incident is subject to compulsory notification. Under Section 70 of the Medical Devices Act, the notification must be made without delay to the Federal Office for Safety in Health Care (BASG). It is

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recommended that the appropriate forms be used for this purpose.

### **Market surveillance of medical devices**

Having placed a device on the market, manufacturers must maintain a system for verifying its continuing marketability. They must actively observe, record and assess whether all of the performance criteria indicated in the specifications and technical documentation are actually achieved and maintained throughout the lifetime of the device (post-market surveillance (PMS) system). In particular, continuous review and assessment of the risk-benefit ratio is indispensable. If it emerges in the course of time that a device is involved in more incidents than had been predicted or anticipated, the manufacturer must initiate appropriate remedial measures.

### **Illegal operations in the medicines and medical devices market**

Every case originates in a suspicion. This suspicion may be communicated to the market surveillance authority by an external source, or it may arise from the authority's own deliberations or investigations. Following an estimation of the health risk posed by the case, all of the relevant facts are collected, and the risk is assessed. On the basis of this risk assessment, the surveillance authority cooperates with a management team with a view to taking a decision as to whether further investigations are warranted on account of the potential danger. In cases where it appears that substantiated charges can be brought without the need for an inspection, a report is sent to the district administrative authorities or the public prosecutor's office after the initial enquiries.

### **Enforcement inspection to confirm a suspicion**

In most cases in which suspicion arises, an on-site inspection, in which samples are generally taken, is necessary in order to establish the precise facts reliably. These investigations are conducted in tandem with the technical inspections.

If serious infringements of the relevant legislation are established during this inspection, the requisite rapid response must be initiated immediately. To ensure that these inspections are conducted quickly and safely, it is necessary in many cases to engage in cooperation with the police, the public health officer and/or the trade office.

### **Charges for confirmed infringements of the law**

If the investigations and the inspection confirm the suspected infringement of the



law, a report containing an exposition of the facts is sent to the competent prosecuting authority. Established dangers to health as well as fraud and falsifications of documents form the basis of criminal charges, which are heard in a court of law. Purely administrative offences are reported to the competent district administrative authorities or town council.

### **Follow-up**

Once the report has been sent, contact is maintained with the prosecuting authorities in order to provide more specific details of the investigations and to explain the wording of the statement of facts. This follow-up serves to keep the surveillance authority informed of developments in the prosecution process while enabling it to assist the prosecuting authorities.<sup>4</sup>

### **Criteria for the selection of products**

See above

### **Cooperation with other authorities**

See above

### **Where surveillance takes place**

See above

### **Forms of surveillance**

See above

### **Product groups scheduled for surveillance**

See above. A sectoral market surveillance plan is drawn up with other European authorities responsible for market surveillance of medical devices.

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<sup>4</sup> Also see: Website of the Federal Office for Safety in Health Care  
[<http://www.basg.at/medizinprodukte/vigilanz-und-marktueberwachung/>]

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## 6.2 Lifts

EU legal provisions	Directive 95/16/EC on lifts
Transposition in Austria	Lifts Safety Regulation 2008 - ASVv 2008, BGBl. II No 274/2008
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/5 Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 5827 (direct dial) Email: post.I5@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints made, for example, by lift users and to notifications from other Member States or the European Commission.

Proactive market surveillance is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) group.

### Criteria for the selection of products

In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Cooperation with other authorities

Cooperation takes place nationally on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance. Provision has been made for accredited bodies (certification, testing and surveillance bodies), official experts and the competent authorities' own inspectorates to deliver technical reports on examined products. In the EU context, cooperation takes place with the market surveillance authorities of the other Member States through the designated national contacts for the product category.

### Where surveillance takes place

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Surveillance takes place at the location where the lift is installed.

### **Forms of surveillance**

An examination is conducted as part of the process of authorising the operation of a lift.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. No such programme is planned for 2016. In addition to these programmes, the market surveillance authorities may intervene as required.

## 6.3 Explosive precursors

EU legal provisions	Regulation (EU) No 98/2013
Accompanying measures in Austria	Chemicals Act 1996 (ChemG 1996), BGBl. I No 53/1997, as amended, Sections 10, 71(1) nos 35 to 40, and 57 et seqq. on surveillance measures Precursors Regulation, BGBl. II No 31/2015 Act on the Federal Criminal Police Office (BKA-G),
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/5 Stubenbastei 5, 1010 Vienna, Austria Telephone: (+43 1) 51522-0 <a href="mailto:service@bmlfuw.gv.at">service@bmlfuw.gv.at</a> Federal Ministry of the Interior (Bundesministerium für Inneres – BM.I),
Market surveillance authority	Governor of the relevant province (indirect federal

### Basic strategy

In September 2014 measures were introduced in Europe that sought to prevent the misuse of explosives in criminal and terrorist acts (Regulation (EU) No 98/2013). The provision of the substances in Annex I of the Regulation to private persons has been prohibited in concentrations above the limit specified therein since 2 September 2014. Substances with lower concentrations than those specified in Annex I of the Regulation remain available without any marketing restrictions. Member States may provide for a complete ban, a registration system and/or an approval system on a national basis. In Austria, the amendment act to modify the Chemicals Act and the Act on the Federal Criminal Police Office (BGBl. I No 14/2015) in conjunction with the Precursors Regulation (BGBl. II No 31/2015) and the ban on provision to private persons created the possibility of a registration system for 3 substances and mixtures that contain these substances. Restricted source materials for explosives must be labelled in accordance with the EU Regulation and national provisions.

A further focal point of the EU Regulation is the establishment of a national contact to which 'suspicious transactions' (purchases or attempts where there is

a reasonable suspicion that the customer may use the chemicals for the illegal manufacture of explosives) and the theft or loss of substantial volumes are to be reported.

### **Criteria for the selection of products**

The European Commission has to prepare a report on the application of this Regulation by 2017; therefore the focal points should be implemented in due time in Austria in order to be able to provide corresponding data. Corresponding surveillance measures under chemicals law are planned for places where these permitted substances may be distributed or used (pharmacies, construction stores, chemical trade, warehouses, chemists, model construction specialists).

### **Cooperation with other authorities**

Market surveillance in this domain is exercised within Austria under the Chemicals Act 1996 by means of indirect federal administration, which means that there are very close ties between the Federal Ministry and the competent departments of the provincial governments (provincial governor). Moreover, this domain is also subject to the Act on the Federal Criminal Police Office (reporting of suspicious transactions involving certain substances). There is therefore also close cooperation with the BMI's reporting office in this respect.

### **Where surveillance takes place**

Distribution facilities (see above) where the permitted substances are distributed may be inspected by the supervisory authorities.

### **Forms of surveillance**

In this respect, Sections 57 et seq. of the Chemicals Act 1996 provide for very far-reaching measures, such as the collection of samples, seizure, communication of classification data and notification of the public in cases of imminent danger.

### **Product groups scheduled for surveillance**

In 2016 surveillance is set to focus on the areas of, for example, pool cleaners, model aeroplane fuels, cleaners, de-rusting agents, descaling agents and oxidation and bleaching agents (together with the BMI reporting office).

## 6.4 Batteries

EU legal provisions	Directive 2013/56/EU on batteries and accumulators and waste batteries and accumulators
Transposition in Austria	Batteries Regulation (Batterienverordnung) 2008 –
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/6  Stubenbastei 5, 1010 Vienna, Austria
Market surveillance authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management

### Basic strategy

Market surveillance of the products in question is exercised nationally; in principle, it is exercised on a proactive basis.

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Criteria for the selection of products

The selection of products is made nationally. It is based, inter alia, on the experiences gathered by Member States through national programmes and complaints.

### Cooperation with other authorities

No ad hoc cooperation takes place with other national authorities.

### Where surveillance takes place

Surveillance is carried out by experts on-site at the premises of the manufacturer, the importer or trader and consists in the removal of a selection of products (batteries).

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## **Forms of surveillance**

Surveillance takes the form of laboratory tests and verification of compliance with marking regulations.

## **Product groups scheduled for surveillance**

For 2016, there are plans to subject some battery types covered by the aforementioned Directive to surveillance; these types have yet to be specified. The types and numbers will be determined in connection with the national selection of companies for examination, which, for reasons of synergy, will involve simultaneous verification of compliance with other statutory orders – the Packaging Regulation (Verpackungsverordnung) and the Used Electrical Equipment Regulation (Elektroaltgeräteverordnung) – as well as the Batteries Regulation.

## 6.5 Construction products under provincial jurisdiction

EU legal provisions	Regulation (EU) No 305/2011 on construction products
Transposition in Austria	<p>Construction Products Act - BauPG, BGBl. I No 55/1997, in the version: BGBl. I No 136/2001</p> <p>Agreement concluded under Article 15a of the Federal Constitution Act on the market surveillance of construction productions</p> <p>Agreement concluded under Article 15a of the Federal Constitution Act on cooperation in construction matters and the making available on the market and use of construction products</p> <p>Corresponding transpositions into provincial legislation:</p> <p>Construction Products and Accreditation (Burgenland) Act (Bürgerländisches Bauprodukte- und Akkreditierungsgesetz), Provincial Law Gazette (LGBl.) No 32/2007, in the version: Provincial Gazette No 79/2013</p> <p>Construction Products (Carinthia) Act (Kärntner Bauproduktegesetz), LGBl. No 46/2013, in the version: Provincial Gazette No 85/2013</p> <p>Construction Products and Market Surveillance (Lower Austria) Act (Niederösterreichisches Bauprodukte- und Marktüberwachungsgesetz) 2013, index No 8204-0, as amended on 11 April 2014</p> <p>Construction Engineering (Upper Austria) Act (Oberösterreichisches Bautechnikgesetz) 2013, LGBl. No 35/2013, in the version: Provincial Gazette No 89/2014</p> <p>Construction Products (Salzburg) Act (Salzburger Bauproduktegesetz), LGBl. No 75/2014, in the version: Provincial Gazette No 60/2015</p> <p>Construction Products and Market Surveillance (Styria) Act (Steiermärkisches Bauprodukte und Marktüberwachungsgesetz) 2013, LGBl. No 83/2013</p>

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	<p>Construction Products (Tyrol) Act (Tiroler Bauproduktegesetz), LGBL. No 95/2001, in the version: Provincial Gazette No 130/2013</p> <p>Construction Products (Vorarlberg) Act (Vorarlberger Bauproduktegesetz), LGBL. No 3/2014</p> <p>Construction Products (Vienna) Act (Wiener Bauproduktegesetz) 2013, LGBL. No 23/2014</p>
Federal contact authority for intergovernmental consultation	<p>Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/11</p> <p>Stubenring 1, 1011 Vienna, Austria</p> <p>Tel.</p> <p>Email: post.I11@bmwfw.gv.at</p>
Market surveillance authorities	<p>Austrian Institute of Construction Engineering (Österreichisches Institut für Bautechnik – OIB)</p> <p>Schenkenstrasse 4, 1010 Vienna, Austria</p> <p>Telephone: +43 1 5336550, Email: mail@oib.or.at</p> <p>District administrative authority or provincial government with local jurisdiction<sup>5</sup></p>

## Basic strategy

Provision has been made for both active and reactive market surveillance. Active market surveillance encompasses selected product groups, while reactive surveillance is exercised on an ad hoc basis. The dissemination of information and public relations activities are a major component of the strategy.

## Criteria for the selection of products

The selection of products is determined by a risk assessment conducted in accordance with EU legislation with due regard to peripheral considerations such as market volume and the need to maximise the impact and cost-effectiveness of surveillance measures. Selection is also guided by information on damage, risks and non-compliant products.

## Cooperation with other authorities

<sup>5</sup> In 2016, the Austrian Institute of Construction Engineering is responsible for market surveillance in respect of construction products for the provinces of Vorarlberg, Upper Austria, Lower Austria, Carinthia, Salzburg, Styria, the Tyrol and Vienna. The other provinces will follow, but in the meantime responsibility remains with their respective district administrative authorities and provincial governments.

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Cooperation and coordination with the market surveillance authorities of the other Member States takes place within the Administrative Cooperation Group on the Construction Products Directive (AdCo CPD). The AdCo CPD met twice in 2015.

Practical cooperation in the field takes place with market surveillance authorities of other Member States and with the Austrian customs and building authorities.

### **Where surveillance takes place**

Surveillance is carried out at the premises of wholesalers, retailers, manufacturers and importers and, where necessary, in the context of customs clearance or e-commerce. Surveillance may also be carried out during use, at construction sites for example.

### **Forms of surveillance**

Verification of proper marking of products is supplemented by the examination of accompanying papers, declarations of performance, certificates, technical documentation and factory production control. Where necessary, samples are taken, and product characteristics are ascertained by means of laboratory tests.

### **Product groups scheduled for surveillance**

Measures for proactive market surveillance are being undertaken in 2016 for wood joint screws in accordance with EN 14592, mineral wool in accordance with EN 13162 and windows and doors in accordance with EN 14351-1.

## 6.6 Detergents

EU legal provisions	Regulation (EC) No 648/2004
Accompanying measures in Austria	Chemicals Act 1996 (ChemG 1996), BGBl. I No 53/1997, as amended, Sections 29 to 34, 67(1) nos 5, 71(1) nos 11 and 57 et seqq. on surveillance measures
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/5  Stubenbastei 5, 1010 Vienna, Austria Telephone: (+43 1) 51522-0 <a href="mailto:service@bmlfuw.gv.at">service@bmlfuw.gv.at</a>
Market surveillance authority	Governor of the relevant province (indirect federal administration)

### Basic strategy

In the mid-1980s Austria already had a law known as the Detergents Act (Waschmittelgesetz), which was later integrated into the new Chemicals Act of 1996. For almost 25 years, the federal ministry responsible for the environment has stored information on the ingredients, applications and market behaviour of this range of products, which has been subject to EU legislation since 2004. In past years, the provinces and the Federal Ministry have both been playing an active part in European classification and labelling inspections of preparations, including safety data sheets (ECLIPS). In addition, the Ministry, in cooperation with the provinces, has developed and implemented Austrian surveillance programmes, focusing, for example, on fabric conditioners and on e-commerce in detergents. Besides the specific provisions of the EC Regulation (see above), detergents are also covered by the other legal rules that apply to chemicals as regards the risk assessment of their properties, their packaging and their proper marking. Surveillance of these characteristics in Austria has been exercised both proactively and, where occurrences so warrant, reactively.

### Criteria for the selection of products

In cases where EU-wide surveillance priorities are set within this product

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category, this naturally determines the selection of products. Experience has shown, however, that Austria has practically no need to set different surveillance priorities. The same traditional range of product groups is to be found in both sales outlets and e-commerce, namely detergents, fabric conditioners and industrial cleaning agents.

### **Cooperation with other authorities**

Market surveillance in this domain is exercised within Austria under the Chemicals Act 1996 by means of indirect federal administration, which means that there are very close ties between the Federal Ministry and the competent departments of the provincial governments (provincial governor). In particular cases, consumer protection and/or product safety, and hence the relevant federal ministries, may also be involved.

### **Where surveillance takes place**

Places of business where detergents are manufactured or distributed may be inspected by the surveillance authorities, and the same applies to importers' business premises.

### **Forms of surveillance**

In this respect, Sections 57 et seqq. of the Chemicals Act 1996 provide for very far-reaching measures, such as the collection of samples, seizure, communication of classification data and notification of the public in cases of imminent danger.

### **Product groups scheduled for surveillance**

There is no surveillance priority for 2016; nevertheless, detergents are subject to routine monitoring by the provincial government authorities, not least because of the numerous provisions laid down in chemicals legislation that apply to detergents.

## 6.7 Pressure equipment

EU legal provisions	Directive 97/23/EC from 19/07/2016: Directive 2014/68/EC on pressure equipment (PED)
Transposition in Austria	Pressure Equipment Regulation (Druckgeräteverordnung) – DGVO BGBl. II, No 426/1999
EU legal provisions	Directive 2010/35/EU on transportable pressure equipment
Transposition in Austria	Transportable Pressure Equipment Regulation (Ortsbewegliche Druckgeräteverordnung) 2011 – ODGVO 2011, BGBl. II, No 239/2011
EU legal provisions	Directive 2009/105/EC from 20/04/2016: Directive 2014/29/EU on simple pressure vessels (SPVD)
Transposition in Austria	Simple Pressure Vessels Regulation (Einfache Druckbehälter-Verordnung), BGBl. No 388/1994
EU legal provisions	Directive 75/324/EEC on aerosol dispensers
Transposition in Austria	Aerosol Dispensers Regulation (Aerosolpackungsverordnung) 2009, BGBl. II, No 314/2009
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/8  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8211 (direct dial) Email: post.I8@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction  Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/8 (coordination)

### Basic strategy

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Pressure equipment comprises both consumer goods and products for industrial use. Market surveillance of pressure equipment in the form of consumer goods is predominantly reactive. Consumer equipment is, however, covered by the proactive European market surveillance campaigns initiated by PED ADCO, the Administrative Cooperation Group on the Pressure Equipment Directive. Since, other than the PED ADCO information, no information regarding non-compliant, defective or dangerous products has been received for years, it is not necessary for the time being to engage in any additional proactive market surveillance.

Market surveillance of pressure equipment and assemblies for industrial use is exercised by means of the mandatory commissioning test conducted by inspection bodies covering all of the formal requirements. There is an obligation to notify the market surveillance authorities. This effectively amounts to 100 % proactive market surveillance.

In principle, then, reactive market surveillance results from complaints, incident reports and other information sources, such as the Communication and Information Resource Centre Administrator (CIRCA), the Information and Communication System on Market Surveillance (ICSMS) or the Community Rapid Information System RAPEX, but also from notifications made by inspection bodies under the Austrian Statistics Regulation.

### **Criteria for the selection of products**

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project. Previous surveillance campaigns and the campaigns planned by PED ADCO target the main consumer goods.

In order to assess the inherent product risk, the risk factors of quantity on the market, hazard potential and manner of placing on the market (with or without a notified body; applicable conformity assessment module) are examined, as is the risk of damage in operation. The notifications made under the Statistics Regulation cover damage and accidents connected with pressure equipment and are the basis for a risk assessment with a view to possible reactive market surveillance measures and/or proactive market surveillance programmes in a particular sector.

### **Cooperation with other authorities**

Close cooperation is practised with the authorities responsible for consumer protection, since the Product Safety Act (Produktsicherheitsgesetz) is subsidiary to instruments governing specific products. Cooperation with the customs authorities takes place through the contact point at the Federal Ministry of

Finance; information accompanied by precise descriptions and photographs is sent and the customs authorities are asked for assistance.

In the EU context, cooperation takes place with the market surveillance authorities of the other Member States within the ADCO PED group.

### **Where surveillance takes place**

Surveillance of consumer goods is primarily carried out in sales outlets; in the case of products for industrial use, surveillance takes place in connection with the commissioning of new equipment or at the location where the equipment is installed and in operation.

### **Forms of surveillance**

Surveillance primarily consists of a visual inspection to check the condition of equipment and of marking and documentation checks. In duly substantiated cases, further examinations by inspection bodies are initiated, involving recalculations and tests.

### **Product groups scheduled for surveillance**

The following products are scheduled to undergo surveillance:

#### 1. Products for which procedures still need to be completed

Both proactive and reactive market surveillance procedures begun in 2015 which still need to be finished must be completed before provision is made for the primarily proactive market surveillance of other products.

#### 2. Products for which risk indications are received

Provision has been made for appropriate reactive market surveillance in such cases, subject to prior examinations if necessary.

## 6.8 Electrical equipment – electromagnetic compatibility

EU legal provisions	Directive 2004/108/EC on electromagnetic compatibility from 20/04/2016: Directive 1014/30/EU
Transposition in Austria	Electromagnetic Compatibility Regulation (Elektromagnetische Verträglichkeitsverordnung) 2006 – EMVV 2006, BGBl. II No 529/2006 from 20/04/2016: Electromagnetic Compatibility Regulation (Elektromagnetische Verträglichkeitsverordnung) 2015 – EMVV 2015
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8225 (direct dial) Email: post.I9@bmwfw.gv.at
Market surveillance authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9

### Basic strategy

Market surveillance of electrical equipment is largely carried out in a proactive manner through participation in market surveillance campaigns initiated by the EU.

Reactive surveillance is mostly initiated in response to complaints about malfunctions.

### Criteria for the selection of products

The selection of products is made in the EU framework when programmes are drawn up. It is based on the experiences gathered by Member States through national programmes and complaints. The final selection is made on the basis of an impact assessment.

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## **Cooperation with other authorities**

Cooperation takes place nationally with the customs authorities on an ad hoc basis. There is also close cooperation with the consumer protection authorities, since these are often the first point of call for users with complaints.

In the European Union there is smooth collegial cooperation with the market surveillance authorities of the other Member States in the firmly established formal framework of EMC ADCO, the Administrative Cooperation Working Group for Electromagnetic Compatibility.

## **Where surveillance takes place**

Surveillance is carried out by inspectors in wholesale and retail trade, and also in cooperation with the customs authorities during customs clearance of goods from non-EU countries; it entails verification of compliance with administrative requirements and, where necessary, testing of products in accredited laboratories.

## **Forms of surveillance**

The primary form of surveillance is visual inspection. Compliance with administrative requirements is also checked; if there are grounds for suspicion, further laboratory readings are taken.

## **Product groups scheduled for surveillance**

Participation in the *1st Joint EMC/LVD ADCO Market Surveillance Campaign*, originally planned for 2015, is scheduled for 2016 (postponed due to administrative problems relating to funding by the European Commission); as part of this both the safety and the EMC aspects of energy-efficient lamps using LED and fluorescent technology will be scrutinised.

## 6.8 Electrical equipment – hazardous substances (RoHS)

EU legal provisions	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), last amended by delegated Regulation 2015/863/EU to amend annex 2
Transposition in Austria	Used Electrical Equipment Regulation (Elektroaltgeräteverordnung) 2005 – Waste Management Act (Abfallwirtschaftsgesetz) 2002, as amended
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/6  Stubenbastei 5, 1010 Vienna, Austria Tel.+43 1 515 22 2550 (direct dial) Email: abt.56@bmlfuw.at
Market surveillance authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/6

### Basic strategy

Market surveillance of the products in question is exercised nationally; in principle, it is exercised on a proactive basis.

Reactive market surveillance is mostly carried out in response to information from competitors.

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Criteria for the selection of products

The selection of products is made nationally, the choice being informed by previous experience, the experiences of other Member States and agreements

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with the market surveillance authorities of the other Member States.

### **Cooperation with other authorities**

No ad hoc cooperation takes place with other national authorities.

In the framework of the European Union, cooperation takes place with the market surveillance authorities of the other Member States in the RoHS Enforcement Network Group.

### **Where surveillance takes place**

Surveillance is carried out on-site by experts in the premises of manufacturers, importers and traders and entails checking the information and documentation that are needed to verify the conformity of equipment and removing selected products (items of electrical equipment).

In the selection of companies for surveillance, consideration is given to the use of synergetic effects through simultaneous verification of compliance with other statutory orders.

### **Forms of surveillance**

Surveillance is carried out by means of laboratory tests and the perusal of documentation as well as through the system of CE marking.

### **Product groups scheduled for surveillance**

In 2016 it is planned to subject certain types of electrical equipment to surveillance. The types and numbers of items will be determined in connection with the national selection of companies for examination, which, for reasons of synergy, will involve simultaneous verification of compliance with other statutory orders — the Packaging Regulation and the Batteries Regulation — as well as the Used Electrical Equipment Regulation.

The surveillance of USB cables is planned for 2016 as part of the RoHS Enforcement Network Group. This will be a joint project involving the market surveillance authorities of other Member States.

## 6.10 Electrical equipment – safety

EU legal provisions	Directive 2006/95/EC on electrical equipment designed for use within certain voltage limits (Low Voltage Directive); from 20/04/2016: Directive 1014/35/EU
Transposition in Austria	Low Voltage Equipment Regulation (Niederspannungsgeräteverordnung) 1995 – NspGV 1995, BGBl. No 51/1995 from 20/04/2016: Low Voltage Equipment Regulation (Niederspannungsgeräteverordnung) 2015 – NspGV 2015
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8225 (direct dial) Email: post.I9@bmwfw.gv.at
Market surveillance authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9

### Basic strategy

Market surveillance of electrical equipment is largely carried out in a proactive manner. In this product category, the European market surveillance campaigns initiated by LVD ADCO, the Administrative Cooperation Working Group on the Low Voltage Directive, are of the utmost importance. In addition, the analysis of the inherent product risk attached to the various types of equipment covered by the Directive serves as a starting point for surveillance activities.

Reactive market surveillance is mostly initiated in response to complaints made by consumers and other users or to CIRCA and RAPEX notifications. It should be noted that no complaints are received from within the trade about competitors.

### Criteria for the selection of products

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

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In order to gauge the inherent risk attached to a product, the risk factors of market penetration, protection rating, number of components in the equipment under relatively high voltage and/or current, percentage of CIRCA and RAPEX notifications that relate to the product category, intentional and unintentional operation and percentage of products with certification marks are assessed. The result is a ranking of products by risk level, which is the basis for surveillance planning. In addition, participation in European market surveillance campaigns is an important element of proactive market surveillance.

### **Cooperation with other authorities**

Cooperation takes place nationally with the customs authorities on an ad hoc basis. There is also close cooperation with the consumer protection authorities, since these are often the first point of call for users with complaints.

In the European Union there is smooth collegial cooperation with the market surveillance authorities of the other Member States in the firmly established formal framework of LVD ADCO, the Administrative Cooperation Working Group on the Low Voltage Directive.

### **Where surveillance takes place**

Surveillance is carried out primarily by inspectors in wholesale and retail trade but also through the internet and in cooperation with the customs authorities during customs clearance of goods from non-EU countries.

### **Forms of surveillance**

The primary form of surveillance is visual inspection. Compliance with administrative requirements is also checked. If there are grounds for suspicion, further laboratory readings are taken.

### **Product groups scheduled for surveillance**

Participation in the *1st Joint EMC/LVD ADCO Market Surveillance Campaign*, originally planned for 2015, is scheduled for 2016 (postponed due to administrative problems relating to funding by the European Commission); as part of this both the safety and the EMC aspects of energy-efficient lamps using LED and fluorescent technology will be scrutinised.

The national surveillance priorities will be set at the beginning of 2016.

## 6.11 Paints

EU legal provisions	Directive 2004/42/EC
Transposition in Austria	Solvents Regulation (Lösungsmittelverordnung) 2005 – LMV 2005, BGBl. II No 398/2005
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/5  Stubenbastei 5, 1010 Vienna, Austria Telephone: +43 (1) 51522-0 <a href="mailto:service@bmlfuw.gv.at">service@bmlfuw.gv.at</a>
Market surveillance authority	Provincial governor with local jurisdiction

### Basic strategy

Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products (Paints Directive) was transposed into domestic law by the Solvents Regulation of 2005 on the basis of the Chemicals Act (Chemiegesetz) 1996. Articles 6 and 7 of the Directive require Member States to set up a monitoring programme for the purpose of verifying compliance with the Directive and to report the results of the programme to the European Commission.

### Criteria for the selection of products

The programme for this priority (2015/2016) has been designed in such a way as to allow the fullest possible overview of the entire distribution chain. As a result, checks are being conducted in the premises of manufacturers, importers, wholesalers, retailers and end users. Care is being taken to ensure that the widest possible spectrum of economic operators involved in trade in paints and varnishes was covered by the inspections. Besides manufacturers of paints and varnishes and paint dealers, operators such as builders' merchants, hardware stores, vehicle-parts dealers and warehouses are subject to surveillance. In order to obtain a statistically meaningful result, multiple samples are being taken of all product types for which the Paints Directive lays down VOC content limits. The distinction between water-based and solvent-based paints is being taken into account. In total, the chemicals inspectors are conducting 100 inspections nationwide, 35 of them in manufacturing facilities, 5 in importers' premises, 30

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in wholesale warehouses and the remainder in retail outlets or at end users' premises.

Besides the taking of samples, the inspections are focusing on verifying that the products are marked in accordance with the Solvents Regulation 2005, which prescribes the following indications:

1. designation of the subcategory and, where appropriate, the way in which this information is presented
2. indication of the VOC limit value for the subcategory in question
3. the maximum VOC content of the product when ready for use.

In addition, checks are being conducted to ensure that the product has been correctly labelled in German and that the labelling complies with general chemicals legislation.

### **Cooperation with other authorities**

Market surveillance in this domain is exercised within Austria under the Chemicals Act 1996 by means of indirect federal administration, which means that there are very close ties between the Federal Ministry and the competent departments of the provincial governments (provincial governor). In particular cases, consumer protection and/or product safety, and hence the relevant federal ministries, may also be involved.

### **Where surveillance takes place**

See above.

### **Forms of surveillance**

In this respect, Sections 57 et seqq. of the Chemicals Act 1996 provide for very far-reaching measures, such as the collection of samples, seizure, communication of classification data and notification of the public in cases of imminent danger.

### **Product groups scheduled for surveillance**

The surveillance priority is to be completed in 2016 in accordance with EU legal requirements.

## 6.12 Radio equipment and telecommunications terminal equipment (R&TTE)

EU legal provisions	<p>Directive 1999/5/EC on radio equipment and telecommunications terminal equipment (R&amp;TTE Directive)</p> <p>Decision 2013/638/EU on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS)</p> <p>Decision 2005/631/EC on access of Cospas-Sarsat locator beacons to emergency services</p> <p>Decision 2005/53/EC on radio equipment intended to participate in the Automatic Identification System (AIS)</p> <p>Decision 2000/637/EC on radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways</p> <p>Decision 2001/148/EC on avalanche beacons</p> <p>Decision 2000/299/EC establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers</p>
Transposition in Austria	<p>Federal Radio Equipment and Telecommunications Terminal Equipment Act (Bundesgesetz über Funkanlagen und Telekommunikationsendeinrichtungen) (FTEG); BGBl. No 134/2001, in the version: BGBl. No 123/2013</p>
Competent federal authority	<p>Federal Ministry of Transport, Innovation and Technology (Bundesministerium für Verkehr, Innovation und Technologie), Directorate-General III, Directorate for Postal and Telecommunications Services</p> <p>Radetzkystrasse 2, 1030 Vienna, Austria</p> <p>Telephone: +43 1 71162 654220 (direct dial)</p> <p>FAX: +43 1 71162 654209 (direct dial)</p> <p>Email: <a href="mailto:pt3@bmvit.gv.at">pt3@bmvit.gv.at</a></p>
Market surveillance authority	Office for Radio Equipment and

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	Telecommunications Terminal Equipment (Büro für Funkanlagen und Telekommunikationsendeinrichtungen) Telecommunications authority of first instance Radetzkystrasse 2, 1030 Vienna, Austria Telephone: +43 0 1 71162 654040 (direct dial) Fax: +43 0 1 71162 654049 (direct dial) Email: <a href="mailto:bftk@bmvit.gv.at">bftk@bmvit.gv.at</a>
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## **Basic strategy**

Market surveillance of radio equipment and telecommunications terminal equipment is carried out both proactively and reactively. The inherent product risk of equipment types is part of the national market surveillance strategy.

Reactive market surveillance measures are mostly taken as a consequence of national checks on operating licences for radio equipment, of consumer complaints, of CIRCA and RAPEX notifications and of relevant information from the market.

The results of the European market surveillance campaigns initiated by the Administrative Cooperation Group for Radio and Telecommunications Terminal Equipment (R&TTE ADCO) have a significant influence on national strategy.

## **Criteria for the selection of products**

At the present time, the selection of products is based primarily on random sampling and relevant information from the market. All checked equipment, regardless of the outcome of the market investigation, is registered and assessed in a dedicated database. These data serve as a criterion for subsequent market investigations.

## **Cooperation with other authorities**

Within Austria, close cooperation takes place with the competent national market surveillance authorities for electromagnetic compatibility and for electrical equipment designed for use within certain voltage limits. Cooperation with the customs authorities takes place on an ad hoc basis.

Within Austria, close cooperation took place with the bodies of the telecommunications authorities (telecommunications offices).

In the European Union there is smooth collegial cooperation with the market surveillance authorities of the other Member States in the firmly established formal framework of R&TTE ADCO, the Administrative Cooperation Working Group for Radio and Telecommunications Terminal Equipment.

There are other special forms of cooperation, particularly with Germany, Switzerland and Luxembourg in the economic area of German-speaking countries.

## **Where surveillance takes place**

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Surveillance is carried out throughout Austrian territory by the bodies of the telecommunications authorities. Inspections are conducted in retail outlets, on suppliers' and manufacturers' premises and, in duly substantiated cases, during customs clearance of products from non-EU countries. Further investigations are conducted on the internet.

### **Forms of surveillance**

The primary form of surveillance is visual inspection. Compliance with administrative requirements is also checked, and, if there are grounds for suspicion, laboratory tests are conducted in accordance with the applicable standards. Monitoring of relevant product groups is also stepped up through an existing national programme.

### **Product groups scheduled for surveillance**

In the light of the provisions of Regulation (EC) No 765/2008, in consultation with the ADCO Member States and in consideration of the ACO campaigns and relevant information from the market, it is planned to focus in 2016 on all types of radio equipment in the frequency bands from 9 kHz to 3 000 GHz and on telecommunications terminal equipment for direct connection to interfaces with public telecommunication networks, although precise details of the market surveillance measures have yet to be specified.

Radio equipment such as PMSE (i.e. radio microphones and in-ear applications), short range devices (e.g. alarm radio equipment, wireless audio applications, RFIDs, etc.), 5 GHz radio products, amateur radio devices, drones and remote-controlled toys are investigated in particular during market surveys.

## 6.13 Appliances burning gaseous fuels

EU legal provisions	Directive 2009/142/EC on appliances burning gaseous fuels
Transposition in Austria	Gas Appliances (Safety) Regulation (Gasgeräte-Sicherheitsverordnung) – GSV BGBl. No 430/1994, last amended by BGBl. II No 15/2007
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/5  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 5827 (direct dial) Email: post.I5@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints made, for example, by users of gas-fired appliances and to notifications from other Member States or the European Commission.

Proactive market surveillance of these products is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) groups.

### Criteria for the selection of products

In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Cooperation with other authorities

Within Austria, cooperation takes place on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance, and with the Federal Ministry of Labour, Social Affairs and Consumer Protection, which is responsible for the application of Directive 2001/95/EC on general product safety. Provision has been made for accredited bodies (certification, testing and surveillance bodies) to deliver technical reports on examined products. In the

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EU context, cooperation takes place with the market surveillance authorities of the other Member States through the designated national contacts for the product category.

### **Where surveillance takes place**

Surveillance is carried out throughout the distribution chain.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declarations of conformity and operating instructions). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. No such programme is planned for 2015. In addition to these programmes, the market surveillance authorities may intervene as required.

## 6.14 Noise emissions by outdoor equipment

EU legal provisions	Directive 2000/14/EC on noise emission in the environment by equipment for use outdoors
Transposition in Austria	Regulation issued by the Federal Minister of the Economy and Labour on Noise Emission in the Environment by Equipment for Use Outdoors (Verordnung des Bundesministers für Wirtschaft und Arbeit über Geräuschemissionen von zur Verwendung im Freien vorgesehenen Geräten und Maschinen), Federal Law Gazette II, No 249/2001
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/5  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 5827 (direct dial) Email: post.I5@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints and to notifications from other Member States or the European Commission.

Proactive market surveillance of these products is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) groups.

### Criteria for the selection of products

In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Cooperation with other authorities

Cooperation takes place nationally on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance. Provision has been made for accredited bodies (certification, testing and surveillance bodies) and official experts to deliver technical reports on examined products. In the

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EU context, cooperation takes place with the market surveillance authorities of the other Member States through the designated national contacts for the product category.

### **Where surveillance takes place**

Surveillance is carried out at every link in the distribution chain.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declarations of conformity and operating instructions). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. In addition to these programmes, the market surveillance authorities may intervene as required.

## 6.15 Wood preservatives

EU legal provisions	Regulation (EU) No 528/2012
Transposition in Austria	Biocidal Products Act (Biozidproduktegesetz), BGBl. I No 105/2013
Competent federal authority	Federal Ministry of Agriculture, Forestry, Environment and Water Management (Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Division V/5  Stubenbastei 5, 1010 Vienna, Austria Telephone: +43 (1) 51522-0 <a href="mailto:service@bmlfuw.gv.at">service@bmlfuw.gv.at</a>
Market surveillance authority	Provincial governor with local jurisdiction

### Basic strategy

Regulation (EU) No 528/2012 concerning the provision on the market and use of biocidal products (EU Biocidal Products Regulation) is implemented at national level through the Biocidal Products Act (Biozidproduktegesetz), BGBl. I No 105/2013. Articles 65 to 68 of the EU Regulation require Member States to set up a monitoring programme for the purpose of verifying compliance with the Regulation and to report the results of the programme to the European Commission.

### Criteria for the selection of products (for this priority)

The wood preservatives sector (product type 8) was selected for the surveillance programme as, based on the EU-wide work programme, the evaluation of active substances in this sector is likely to be completed next year. The concept for this priority essentially envisages the permit requirement for wood preservatives being checked on the basis of the authorisation date of the active substance, and then the classification and labelling in accordance with the authorisation notice under the Biocidal Products Act or the CLP and Reach Regulations being subjected to a comprehensive review. The checks should also make it possible to gain a better overview of the entire distribution chain. As a result, checks are being conducted in the premises of manufacturers, importers, wholesalers, retailers and end users. A total of 20–30 controls will be carried out across Austria by the chemicals inspectorates.

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Wood preservatives are to be examined using sampling and subsequent analyses to ensure that the products only contain authorised active substances.

### **Cooperation with other authorities**

Market surveillance in this domain is exercised within Austria under the Biocidal Products Act 2013 by means of indirect federal administration, which means that there are very close ties between the Federal Ministry and the competent departments of the provincial governments (provincial governor). In particular cases, consumer protection and/or product safety, and hence the relevant federal ministries, may also be involved.

### **Where surveillance takes place**

See above.

### **Forms of surveillance**

In this respect, Sections 15 et seqq. of the Biocidal Products Act 2003 and Sections 57 et seqq. of the Chemicals Act 1996 provide for very far-reaching measures, such as the collection of samples, seizure, communication of classification data and notification of the public in cases of imminent danger.

### **Product groups scheduled for surveillance**

The surveillance priority will be completed in 2016. However, the existing practice of routine inspections will be continued.

## 6.16 In vitro diagnostic medical devices

EU legal provisions	Directive 98/79/EC on in vitro diagnostic medical devices
Transposition in Austria	Medical Devices Act – MPG, BGBl. No 657/1996 as amended
Competent federal authority	Federal Ministry of Health (Bundesministerium für Gesundheit) Division III/3  Radetzkystrasse 2, 1030 Vienna, Austria Tel. +43-1/711 00-4602  Email: meddev@bmg.gv.at
Market surveillance authority	Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen)  Traisengasse 5, 1200 Vienna, Austria Tel. Email: medizinprodukte@basg.gv.at www.basg.gv.at

### Basic strategy

Risk-based system.

Market surveillance by the Federal Office for Safety in Health Care (BASG) comprises both reactive and proactive surveillance.

#### 1. Reactive market surveillance

##### Systematic vigilance

Reactive market surveillance is based on a statutory notification requirement. Under Section 70(1) and (3) of the Medical Devices Act, all serious incidents are to be reported to the BASG without delay as soon as a causal link is established between a malfunction or failure of a medical device and the occurrence of the incident. If this link is not evident, the manufacturer must investigate the existence of such a link and report its findings to the BASG within ten days.

##### Remedial measures in the field

If the analysis of the cause of the incident reported to the BASG reveals a new systemic problem that poses an unreasonable risk to the Austrian and European

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markets, a remedial measure is taken in the field in Austria, that is to say the recall of the devices or batch in question or the communication of safety information to all users of the devices, in order to reduce any risk to patients, users or third parties. Under Section 77(2) of the Medical Devices Act, the BASG informs the other Member States of these remedial measures in the framework of a National Competent Authority Report (NCAR) with a view to ensuring that these measures are implemented throughout the European Economic Area.

If the BASG is informed by Austrian manufacturers of the initiation of a remedial measure which is not attributable to a specific incident, the EU Member States are informed in this case too by means of an NCAR in accordance with Section 77(2) of the Medical Devices Act.

### Certificates of free sale

When applications are made for the issue of a certificate of free sale, the definition and classification of the device, as well as its marking, are checked for compliance with the statutory requirements.

## **2. Proactive market surveillance**

### Surveillance cases

In these cases, the focus is primarily on verifying that devices are properly defined and classified and bear the proper markings.

### Inspections:

In addition, an inspection is conducted to verify in the field the findings set out in the exposition of the facts.

## **Safety alerts and safety information**

### 1. Safety alerts

Safety alerts are warnings about a clear and present danger to the life and limb of a patient, user or third party arising from the malfunctioning of a medical device. In order to reduce such a specific risk, a safety alert is drawn up by the BASG. This is published on the BASG website and, with due regard to the inherent risks within the market, is publicised, typically by being sent to the provincial health boards for distribution to hospitals and doctors' surgeries.

### 2. Safety information

Safety information is information material which draws attention to a general risk and is not normally restricted to a specific device on the Austrian market. This risk can normally be mitigated by exercising particular care, observing specific precautions or the like. The need to respond to safety information is typically somewhat less urgent. It is also disseminated by means of publication on the BASG website and — depending on the level of urgency and the diffusion of the

relevant devices — by means of e-mails.

### **Systematic vigilance with regard to medical devices**

Serious incidents involving medical devices, including in vitro diagnostic devices, as well as near misses must be reported to the competent authority. Even the possibility that a medical device was partly to blame for a serious incident is subject to compulsory notification. Under Section 70 of the Medical Devices Act, the notification must be made without delay to the Federal Office for Safety in Health Care (BASG). It is recommended that the appropriate forms be used for this purpose.

### **Market surveillance of medical devices**

Having placed a device on the market, manufacturers must maintain a system for verifying its continuing marketability. They must actively observe, record and assess whether all of the performance criteria indicated in the specifications and technical documentation are actually achieved and maintained throughout the lifetime of the device (post-market surveillance (PMS) system). In particular, continuous review and assessment of the risk-benefit ratio is indispensable. If it emerges in the course of time that a device is involved in more incidents than had been predicted or anticipated, the manufacturer must initiate appropriate remedial measures.

### **Illegal operations in the medicines and medical devices market**

Every case originates in a suspicion. This suspicion may be communicated to the market surveillance authority by an external source, or it may arise from the authority's own deliberations or investigations. Following an estimation of the health risk posed by the case, all of the relevant facts are collected, and the risk is assessed. On the basis of this risk assessment, the surveillance authority cooperates with a management team with a view to taking a decision as to whether further investigations are warranted on account of the potential danger. In cases where it appears that substantiated charges can be brought without the need for an inspection, a report is sent to the district administrative authorities or the public prosecutor's office after the initial enquiries.

### **Enforcement inspection to confirm a suspicion**

In most cases in which suspicion arises, an on-site inspection, in which samples are generally taken, is necessary in order to establish the precise facts reliably. These investigations are conducted in tandem with the technical inspections. If serious infringements of the relevant legislation are established during this inspection, the requisite rapid response must be initiated immediately. To ensure that these inspections are conducted quickly and safely, it is necessary in many

cases to engage in cooperation with the police, the public health officer and/or the trade office.

### **Charges for confirmed infringements of the law**

If the investigations and the inspection confirm the suspected infringement of the law, a report containing an exposition of the facts is sent to the competent prosecuting authority. Established dangers to health as well as fraud and falsifications of documents form the basis of criminal charges, which are heard in a court of law. Purely administrative offences are reported to the competent district administrative authorities or town council.

### **Follow-up**

Once the report has been sent, contact is maintained with the prosecuting authorities in order to provide more specific details of the investigations and to explain the wording of the statement of facts. This follow-up serves to keep the surveillance authority informed of developments in the prosecution process while enabling it to assist the prosecuting authorities.<sup>6</sup>

### **Criteria for the selection of products**

See above.

### **Cooperation with other authorities**

See above.

### **Where surveillance takes place**

See above.

### **Forms of surveillance**

See above.

### **Product groups scheduled for surveillance**

See above. A sectoral market surveillance plan is drawn up with other European authorities responsible for market surveillance of medical devices.

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<sup>6</sup> Also see: Website of the Federal Office for Safety in Health Care  
[<http://www.basg.at/medizinprodukte/vigilanz-und-marktueberwachung/>]

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## 6.17 Cosmetics

EU legal provisions	Regulation (EC) No 1223/2009 on cosmetic products Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products
Transposition in Austria	Lebensmittelsicherheits- und Verbraucherschutzgesetz (Food Safety and Consumer Protection Act) BGBl. I 13/2006, as amended  Cosmetics Implementing Regulation (Kosmetik-Durchführungsverordnung), BGBl. II No 2013/330
Competent federal authority	Federal Ministry of Health (Bundesministerium für Gesundheit) Division II/B/14  Radetzkystasse 2, 1030 Vienna, Austria Telephone: +43 1/711 00 4872 (direct dial) Email: IIB14@bmg.gv.at
Market surveillance authority	Provincial authority with local jurisdiction

### Basic strategy

Surveillance of cosmetic products is carried out in the framework of the control plan (sampling and audit plan), the focal points of which generally change from year to year. A large proportion of the samples are obtained from targeted actions. To this end, the Federal Ministry of Health issues general circulars containing precise instructions as to the number of samples of particular cosmetic products to be taken by the food-safety authorities from specified product categories within a specified period. In addition, targeted actions are implemented in which the legally required documentation held by manufacturers and importers of cosmetic products is checked.

### Criteria for the selection of products

Risk-based monitoring, internet and market research, European Commission requirements in some cases and selection based on RAPEX notifications (targeted actions).

### Cooperation with other authorities

Upon request, there may be cooperation with the Federal Ministry of Labour,

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Social Affairs and Consumer Protection or the customs authorities.

### **Where surveillance takes place**

Surveillance takes place in retail outlets, wholesale warehouses and manufacturing facilities and in the context of import controls.

### **Forms of surveillance**

The emphasis is on proactive planning of market surveillance in the form of sampling plans, reactive surveillance in the form of checks on suspect samples and proactive/reactive surveillance in the form of targeted actions.

### **Product groups scheduled for surveillance**

In addition to general spot checks, in particular cosmetic products with hemp, products that are advertised as 'fragrance-free', cosmetics at trade fairs and markets or hair products with N-nitrosodiethanolamine (NDELA).

## 6.18 Food contact materials

EU legal provisions	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (Framework Regulation)  Individual instruments (European Regulations and Directives)
Transposition in Austria	Lebensmittelsicherheits- und Verbraucherschutzgesetz (Food Safety and Consumer Protection Act) BGBl. I 13/2006, as amended
Competent federal authority	Federal Ministry of Health (Bundesministerium für Gesundheit – BMG), Division II/B/14,  Radetzkystrasse 2, 1030 Vienna, Austria Telephone: +43 1/711 00 4792 (direct dial)  Email: IIB14@bmg.gv.at
Market surveillance authority	Provincial authority with local jurisdiction

### Basic strategy

Surveillance of materials and articles intended to come into contact with food (food-contact materials — FCMs) is carried out in the same way as surveillance of foodstuffs themselves, namely in the framework of the national control plan (audit and sampling plan), for which new focal points are set every year. Consequently, some of the sampling is carried out by means of targeted actions. To this end, the Federal Ministry of Health issues general circulars containing precise instructions as to the number of samples of particular FCMs to be taken by the food safety authorities within a specified period. In addition, there is a need to respond to notifications from the European Rapid Alert System for Food and Feed (RASFF).

### Criteria for the selection of products

Risk-based approach, monitoring to maintain an overview of the market, possibly European Commission requirements in some cases and selection based on RASFF notifications and targeted actions.

### Cooperation with other authorities

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Cooperation may take place with the customs authorities on request.

### **Where surveillance takes place**

Nationwide, no information available.

### **Forms of surveillance**

Surveillance of FCMs takes place in the framework of the annual control plan (audit and sampling plan), the focal points of which generally change from year to year. The emphasis is on proactive planning of market surveillance in the form of sampling plans, reactive surveillance in the form of checks on suspect samples and proactive/reactive surveillance in the form of targeted actions. Company audits, for example of FCM users and manufacturers, are also conducted. Conformity checks (company audits and extensive examination of documents) account for an increasing proportion of surveillance activity.

### **Product groups scheduled for surveillance**

In addition to ongoing necessary surveillance activities, priorities for 2016 will be the surveillance of any migration of metals from crockery, items made from natural materials that come into contact with foodstuffs, plastic cans, bottles and objects. Another surveillance target that has been set is GMP and documentation at the premises of FCM (manufacturers, processors, importers).

## 6.19 Machinery

EU legal provisions	Directive 2006/42/EC on machinery
Transposition in Austria	Machinery Safety Regulation (Maschinen-Sicherheitsverordnung) 2010 – MSV 2010, BGBl. II No 282/2008
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/5  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 5827 (direct dial) Email: post.I5@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints and to notifications from other Member States or the European Commission.

Proactive market surveillance of these products is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) groups.

### Criteria for the selection of products

In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Cooperation with other authorities

Within Austria, cooperation takes place on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance, and with the Federal Ministry of Labour, Social Affairs and Consumer Protection, which is responsible for occupational health and safety and for the application of Directive 2001/95/EC on general product safety. Provision has been made for accredited bodies (certification, testing and surveillance bodies) and official experts to deliver technical reports on examined products. In the EU context, cooperation takes place with the market surveillance authorities of the other Member States through the designated national contacts for the product

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category.

### **Where surveillance takes place**

Surveillance is carried out at every link in the distribution chain.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declarations of conformity and operating instructions). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. Planned national surveillance activities for 2016 will focus on motorised chainsaws and vehicle lifting platforms.

## 6.20 Medical devices

EU legal provisions	Directive 93/42/EEC concerning medical devices
Transposition in Austria	Medical Devices Act – MPG, BGBl. No 657/1996 as amended
Competent federal authority	Federal Ministry of Health (Bundesministerium für Gesundheit) Division III/3  Radetzkystrasse 2, 1030 Vienna, Austria Tel. +43-1/711 00-4602  Email: meddev@bm.g.v.at
Market surveillance authority	Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen)  Traisengasse 5, 1200 Vienna, Austria Tel. Email: medizinprodukte@basg.g.v.at www.basg.g.v.at

### Basic strategy

Risk-based system.

Market surveillance by the Federal Office for Safety in Health Care (BASG) comprises both reactive and proactive surveillance.

#### 1. Reactive market surveillance

##### Systematic vigilance

Reactive market surveillance is based on a statutory notification requirement. Under Section 70(1) and (3) of the Medical Devices Act, all serious incidents are to be reported to the BASG without delay as soon as a causal link is established between a malfunction or failure of a medical device and the occurrence of the incident. If this link is not evident, the manufacturer must investigate the existence of such a link and report its findings to the BASG within ten days.

##### Remedial measures in the field

If the analysis of the cause of the incident reported to the BASG reveals a new systemic problem that poses an unreasonable risk to the Austrian and European markets, a remedial measure is taken in the field in Austria, that is to say the

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recall of the devices or batch in question or the communication of safety information to all users of the devices, in order to reduce any risk to patients, users or third parties. Under Section 77(2) of the Medical Devices Act, the BASG informs the other Member States of these remedial measures in the framework of a National Competent Authority Report (NCAR) with a view to ensuring that these measures are implemented throughout the European Economic Area.

If the BASG is informed by Austrian manufacturers of the initiation of a remedial measure which is not attributable to a specific incident, the EU Member States are informed in this case too by means of an NCAR in accordance with Section 77(2) of the Medical Devices Act. Certificates of free sale

When applications are made for the issue of a certificate of free sale, the definition and classification of the device, as well as its marking, are checked for compliance with the statutory requirements.

## **2. Proactive market surveillance**

### Surveillance cases

In these cases, the focus is primarily on verifying that devices are properly defined and classified and bear the proper markings.

#### Inspections:

In addition, an inspection is conducted to verify in the field the findings set out in the exposition of the facts.

## **Safety alerts and safety information**

### 1. Safety alerts

Safety alerts are warnings about a clear and present danger to life and limb of a patient, user or third party arising from the malfunctioning of a medical device. In order to reduce such a specific risk, a safety alert is drawn up by the BASG. This is published on the BASG website and, with due regard to the inherent risks within the market, is publicised, typically by being sent to the provincial health boards for distribution to hospitals and doctors' surgeries.

### 2. Safety information

Safety information is information material which draws attention to a general risk and is not normally restricted to a specific device on the Austrian market. This risk can normally be mitigated by exercising particular care, observing specific precautions or the like. The need to respond to safety information is typically somewhat less urgent. It is also disseminated by means of publication on the BASG website and — depending on the level of urgency and the diffusion of the relevant devices — by means of e-mails.

## **Systematic vigilance with regard to medical devices**

Serious incidents involving medical devices as well as near misses must be reported to the competent authority. Even the possibility that a medical device was partly to blame for a serious incident is subject to compulsory notification. Under Section 70 of the Medical Devices Act, the notification must be made without delay to the Federal Office for Safety in Health Care (BASG). It is recommended that the appropriate forms be used for this purpose.

## **Market surveillance of medical devices**

Having placed a device on the market, manufacturers must maintain a system for verifying its continuing marketability. They must actively observe, record and assess whether all of the performance criteria indicated in the specifications and technical documentation are actually achieved and maintained throughout the lifetime of the device (post-market surveillance (PMS) system). In particular, continuous review and assessment of the risk-benefit ratio is indispensable. If it emerges in the course of time that a device is involved in more incidents than had been predicted or anticipated, the manufacturer must initiate appropriate remedial measures.

## **Illegal operations in the medicines and medical devices market**

Every case originates in a suspicion. This suspicion may be communicated to the market surveillance authority by an external source, or it may arise from the authority's own deliberations or investigations. Following an estimation of the health risk posed by the case, all of the relevant facts are collected, and the risk is assessed. On the basis of this risk assessment, the surveillance authority cooperates with a management team with a view to taking a decision as to whether further investigations are warranted on account of the potential danger. In cases where it appears that substantiated charges can be brought without the need for an inspection, a report is sent to the district administrative authorities or the public prosecutor's office after the initial enquiries.

## **Enforcement inspection to confirm a suspicion**

In most cases in which suspicion arises, an on-site inspection, in which samples are generally taken, is necessary in order to establish the precise facts reliably. These investigations are conducted in tandem with the technical inspections. If serious infringements of the relevant legislation are established during this inspection, the requisite rapid response must be initiated immediately. To ensure that these inspections are conducted quickly and safely, it is necessary in many

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cases to engage in cooperation with the police, the public health officer and/or the trade office.

### **Charges for confirmed infringements of the law**

If the investigations and the inspection confirm the suspected infringement of the law, a report containing an exposition of the facts is sent to the competent prosecuting authority. Established dangers to health as well as fraud and falsifications of documents form the basis of criminal charges, which are heard in a court of law. Purely administrative offences are reported to the competent district administrative authorities or town council.

### **Follow-up**

Once the report has been sent, contact is maintained with the prosecuting authorities in order to provide more specific details of the investigations and to explain the wording of the statement of facts. This follow-up serves to keep the surveillance authority informed of developments in the prosecution process while enabling it to assist the prosecuting authorities.<sup>7</sup>

### **Criteria for the selection of products**

See above.

### **Cooperation with other authorities**

See above.

### **Where surveillance takes place**

See above.

### **Forms of surveillance**

See above.

### **Product groups scheduled for surveillance**

See above. A sectoral market surveillance plan is drawn up with other European authorities responsible for market surveillance of medical devices.

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<sup>7</sup> Also see: Website of the Federal Office for Safety in Health Care  
[<http://www.basg.at/medizinprodukte/vigilanz-und-marktueberwachung/>]

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## 6.21 Measuring instruments

EU legal provisions	<p>Directive 90/384/EEC (codified version: Directive 2009/23/EC) on non-automatic weighing instruments, Directive 2014/31/EU</p> <p>Directive 2004/22/EC on measuring instruments, Directive 2014/32/EU</p> <p>Directive 71/316/EEC (codified version: Directive 2009/34/EC) relating to common provisions for both measuring instruments and methods of metrological control</p>
Transposition in Austria	<p>Weights and Measures Act (Maß- und Eichgesetz) BGBl. No 152/1950, as amended</p> <p>Measuring Instruments Regulation (Messgeräteverordnung) BGBl. II No 274/2006</p> <p>Regulation on Conformity Verification Procedures for Non-automatic Weighing Instruments (Verordnung zur Festlegung von Konformitätsfeststellungsverfahren für Nichtselbsttätige Waagen), BGBl. No 751/1994</p> <p>Metrology provisions specific to measuring instruments adopted by the Federal Office of Metrology and Surveying (Bundesamt für Eich- und Vermessungswesen)</p>
Competent federal authority	<p>For the national Regulations:</p> <p>Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/11</p> <p>Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8233 (direct dial) Email: post.I11@bmwfw.gv.at</p>
	<p>For weights and measures legislation:</p> <p>Federal Office of Metrology and Surveying (Bundesamt für Eich- und Vermessungswesen)</p> <p>Arltgassee 35, 1160 Vienna, Austria</p>

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	Tel.+43 1 21110 6335 (direct dial) Email: kanzlei.gruppe.e@bev.gv.at
Market surveillance authority	Federal Office of Metrology and Surveying (Bundesamt für Eich- und Vermessungswesen)  Schiffamtsgasse 1-3, 1020 Vienna, Austria Tel.+43 1 21110 3715 (direct dial) Email: kanzlei.gruppe.a@bev.gv.at  Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/11  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8233 (direct dial) Email: post.I11@bmwfw.gv.at

## Basic strategy

Market surveillance of measuring instruments is largely carried out in a proactive manner on the basis of a programme drawn up by the Federal Office of Metrology and Surveying. At the present time, these activities are coordinated by WELMEC WG 5 ([www.welmec.org](http://www.welmec.org)). This working group has the status of an administrative cooperation (ADCO) group. A forum on market surveillance of measuring instruments has been created in the CIRCA system of the European Commission. Previous practical experience of market surveillance in the field of measuring instruments is the starting point for its deliberations.

Reactive market surveillance is mostly initiated in response to complaints made by consumers and other users or to CIRCA and RAPEX notifications.

## Criteria for the selection of products

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

The risk attached to a product is gauged on the basis of consumer complaints, examination findings, the way in which the product is placed on the market and the importance to the end user of the performance criteria measured by the product. The result is a ranking of products by risk level, which is the basis for surveillance planning. In addition, participation in European market surveillance campaigns is an important element of proactive market surveillance.

## Cooperation with other authorities

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There is currently a limited degree of cooperation with the customs authorities, but it can be intensified whenever the need arises.

European cooperation takes place in the framework of WELMEC WG 5, which functions as an ADCO in the context of cooperation with the European Commission.

### **Where surveillance takes place**

Surveillance is carried out at every stage in the supply chain, on instruments in the possession of traders, importers and end users, as well as on the internet.

### **Forms of surveillance**

First, a visual inspection and a formal review of the administrative requirements for the measuring instrument are carried out. If there are grounds for suspicion, technical inspections are conducted on site or at a specialist laboratory belonging to the Federal Office of Metrology and Surveying (Bundesamt für Eich- und Vermessungswesen — BEV).

### **Product groups scheduled for surveillance**

The surveillance of fuel dispensing pumps, pallet trucks with scales, tape measures and new measuring instruments discovered as part of the audit is planned for 2016. In addition, the EU-funded international 'heat meters' market surveillance project will be completed by mid-2016.

## 6.22 Ecodesign

EU legal provisions	<p>Directive 2005/32/EC on ecodesign requirements for energy-using products</p> <ol style="list-style-type: none"> <li>1) Regulation (EC) No 1275/2008 on ecodesign requirements for standby and off-mode electrical power consumption</li> <li>2) Regulation (EC) No 107/2009 on ecodesign requirements for simple set-top boxes</li> <li>3) Regulation (EC) No 244/2009 on ecodesign requirements for non-directional household lamps</li> <li>4) Regulation (EC) No 245/2009 on ecodesign requirements for fluorescent lamps without ballast, for high-intensity discharge lamps and for ballasts and luminaires able to operate such lamps</li> <li>5) Regulation (EC) No 278/2009 on ecodesign requirements for no-load-condition electric power consumption</li> <li>6) Regulation (EC) No 640/2009 on ecodesign requirements for electric motors</li> <li>7) Regulation (EC) No 641/2009 on ecodesign requirements for glandless circulators</li> <li>8) Regulation (EC) No 642/2009 on ecodesign requirements for televisions</li> <li>9) Regulation (EC) No 643/2009 on ecodesign requirements for household refrigerating appliances</li> <li>10) Regulation (EC) No 327/2011 on ecodesign requirements for fans driven by motors</li> <li>11) Regulation (EC) No 640/2009 on ecodesign requirements for electric motors</li> <li>12) Regulation (EC) No 1015/2010 on ecodesign requirements for household washing machines</li> <li>13) Regulation (EC) No 1016/2010 on ecodesign requirements for household dishwashers</li> <li>14) Regulation (EC) No 641/2009 on ecodesign requirements for glandless circulators</li> <li>15) Regulation (EU) No 547/2012 on ecodesign requirements for water pumps</li> <li>16) Regulation (EU) No 206/2012 on ecodesign</li> </ol>
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		<p>requirements for household tumble driers</p> <p>17) Regulation (EU) No 932/2012 on ecodesign requirements for air conditioners and comfort fans</p> <p>18) Regulation (EU) No 1194/2012 on ecodesign requirements for directional lamps, light emitting diode lamps and related equipment</p> <p>19) Regulation (EU) No 617/2013 on ecodesign requirements for computers and computer servers</p> <p>20) Regulation (EU) No 666/2013 on ecodesign requirements for vacuum cleaners</p> <p>21) Regulation (EU) No 813/2013 on ecodesign requirements for space heaters and combination heaters</p> <p>22) Regulation (EU) No 814/2013 on ecodesign requirements for water heaters and hot water storage tanks</p> <p>23) Regulation (EU) No 66/2014 on domestic ovens, hobs and range hoods</p> <p>24) Regulation (EU) No 548/2014 on transformers</p> <p>25) Regulation (EU) No 1253/2014 on ventilation units</p> <p>26) Regulation (EU) 2015/1095 on commercial cold storage cabinets</p> <p>27) Regulation (EU) 2015/1188 on local space heaters</p>
Transposition Austria	in	Ecodesign Regulation (Ökodesign-Verordnung – ODV) 2007, BGBl. II No 126/2007
Competent authority	federal	<p>Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9</p> <p>Stubenring 1, 1011 Vienna, Austria</p> <p>Tel. +43 1 711 00 8225 (direct dial)</p> <p>Email: post.I9@bmwfw.gv.at</p>
Market authority	surveillance	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9

## Basic strategy

In the realm of proactive market surveillance, the utmost importance is attached to the European market surveillance campaigns initiated by EDD ADCO, the Ecodesign Market Surveillance Administrative Cooperation group.

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Since existing warehouse stock may be sold off without time limit, surveillance of products is not supposed to begin until a reasonable period has elapsed since the entry into force of the relevant energy-efficiency tier.

### **Criteria for the selection of products**

In the event of participation in European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project. Otherwise, the choice is guided by alerts and other information.

### **Cooperation with other authorities**

Cooperation takes place nationally with the customs authorities on an ad hoc basis.

### **Where surveillance takes place**

Surveillance is carried out by inspectors in wholesale and retail trade but also through the internet.

### **Forms of surveillance**

The primary form of surveillance entails checking compliance with administrative requirements; if there are grounds for suspicion, laboratory readings are taken.

### **Product groups scheduled for surveillance**

Participation in a European market surveillance project focusing on the surveillance of ecodesign requirements for directional lamps, light emitting diode lamps and related equipment is planned for 2016.

## 6.23 Personal protective equipment

EU legal provisions	Directive 89/686/EEC Directive 93/68/EEC Directive 93/95/EEC Directive 96/58/EC PPE Directive
Transposition in Austria	Personal Protective Equipment (Safety) Regulation (PSA-Sicherheitsverordnung – PSASV) BGBl. No 596/1994, last amended by Federal Act BGBl. I No 161/2006
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/5  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 5827 (direct dial) Email: post.I5@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints made, for example, by users and to notifications from other Member States or the European Commission.

Proactive market surveillance of these products is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) groups.

### Criteria for the selection of products

In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### Cooperation with other authorities

Within Austria, cooperation takes place on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance, and with the Federal Ministry of Labour, Social Affairs and Consumer Protection, which is

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responsible for the application of Directive 2001/95/EC on general product safety. Provision has been made for accredited bodies (certification, testing and surveillance bodies) and official experts to deliver technical reports on examined products. In the EU context, cooperation takes place with the market surveillance authorities of the other Member States through the designated national contacts for the product category.

### **Where surveillance takes place**

Surveillance is carried out primarily at workplaces and in wholesale warehouses and retail outlets.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declaration of conformity). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. The national priority surveillance target for 2016 is work gloves and respiratory masks.

## 6.24 Products for use in potentially explosive atmospheres (ATEX products)

EU legal provisions	Directive 94/9/EC on equipment and protective systems intended for use in potentially explosive atmospheres (ATEX Directive) from 20/04/2016: Directive 1014/34/EU
Transposition in Austria	Protection from Explosions Regulation (Explosionsschutzverordnung) 1996 – ExSV 1996, BGBl. No 252/1996  from 20/04/2016: Protection from Explosions Regulation (Explosionsschutzverordnung) 2015 – ExSV 2015
Competent federal authority	For electrical ATEX products:  Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8225 (direct dial) Email: post.I9@bmwfw.gv.at
Market surveillance authority for electrical ATEX products	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9
Market surveillance authority for mechanical ATEX products	District administrative authority with local jurisdiction

### Basic strategy

Market surveillance of the products in question is exercised nationally on a reactive basis. It is primarily carried out on an ad hoc basis in response to accidents as well as to complaints made, for example, by users and to notifications from other Member States or the European Commission.

Proactive market surveillance of these products is carried out in the context of European market surveillance campaigns initiated by the relevant Administrative Cooperation (ADCO) groups.

### Criteria for the selection of products

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In the case of the European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project.

### **Cooperation with other authorities**

Cooperation takes place nationally on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance. Provision has been made for accredited bodies (certification, testing and surveillance bodies) and official experts to deliver technical reports on examined products. In the EU context, cooperation takes place with the market surveillance authorities of the other Member States, especially those of the Federal Republic of Germany.

### **Where surveillance takes place**

Surveillance is carried out primarily at workplaces and in manufacturers' premises.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declarations of conformity and operating instructions). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for proactive surveillance is based, in principle, on the ADCO programmes. No such programme is planned for 2016.

## 6.25 Pyrotechnic articles

EU legal provisions	Directive 2007/23/EC on the placing on the market of pyrotechnic articles
Transposition in Austria	Transposition in Austria I No 131/2009
Competent federal authority	Federal Ministry of the Interior (Bundesministerium für Inneres – BM.I)  1010 Vienna, Herrengasse 7 Tel. +43 1 531 26 3989 (direct dial) Email: BMI-III-3@bmi.gv.at
Market surveillance authority	Pyrotechnics authority with local jurisdiction: district administrative authority. In the territory of a municipality in which the provincial police headquarters is also the safety authority of first instance, the provincial police headquarters is the market surveillance authority.  Vienna Provincial Police Headquarters (Landespolizeidirektion Wien)  Schottenring 7–9, 1010 Vienna, Austria Telephone: +43 (1) 31310 Email: Landespolizeidirektion-w@polizei.gv.at  Lower Austria Provincial Police Headquarters (Landespolizeidirektion Niederösterreich)  Linzer Strasse 47, 3100 St. Pölten, Austria Telephone: +43 2742 803 Email: Landespolizeidirektion-n@polizei.gv.at  Lower Austria Provincial Police Headquarters – Schwechat Divisional HQ (Polizeikommissariat Schwechat)  Wiener Strasse 13, 2320 Schwechat, Austria Telephone: +43 1 70150 Email: bpd-sw-praesidialreferat@polizei.gv.at  Lower Austria Provincial Police Headquarters – Wiener Neustadt Divisional HQ (Polizeikommissariat Wiener Neustadt)  Burgplatz 2, 2700 Wiener Neustadt, Austria

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## **Basic strategy**

The Explosives Act 2010 provides for both reactive and proactive market surveillance measures.

## **Criteria for the selection of products**

The selection of products is guided by the pyrotechnic articles that are being purchased in the market and by reports of any defective products.

## **Cooperation with other authorities**

Provision is made in the Pyrotechnic Articles Act for cooperation with the customs authorities.

## **Where surveillance takes place**

Surveillance activities are essentially focused on importers' and traders' warehouses and on retail premises and stalls.

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## **Forms of surveillance**

Market surveillance is carried out locally by the market surveillance authorities of first instance, chiefly by means of visual inspection and perusal of the available documentation to verify compliance with the administrative requirements.

## **Product groups scheduled for surveillance**

No specific surveillance of particular product groups is planned for 2016. Surveillance is exercised in the context of the statutory verification and in response to relevant information from the market.

## 6.26 Marine equipment

EU legal provisions	Directive 96/98/EC Directive 2002/75/EC amending <del>Directive 96/98/EC (Marine Equipment Directive)</del>
Transposition in Austria	Marine Equipment Regulation (Schiffsausrüstungsverordnung)
Competent federal authority	Under discussion <sup>8</sup>
Market surveillance authority	Under discussion

### Basic strategy

Since the Austrian maritime shipping register has been closed for commercial vessels, market surveillance under the Marine Equipment Directive has very little practical relevance.

<sup>8</sup> The Marine Equipment Regulation was enacted on the basis of Section 7(4) of the Maritime Transport (International Compliance) Act (Seeschiffahrts-Erfüllungsgesetz) – SSEG, BGBl. No 387/1996. The Federal Minister for Science, Transport and the Arts (Bundesminister für Wissenschaft, Verkehr und Kunst) was tasked with implementing this Regulation.

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## 6.27 Cableways

EU legal provisions	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008  Directive 2000/9/EC of the European Parliament and of the Council relating to cableway installations designed to carry persons
Transposition in Austria	Cableways Act (Seilbahngesetz) 2003 and direct application of the EU Regulation
Competent federal authority	Federal Ministry of Transport, Innovation and Technology (Bundesministerium für Verkehr, Innovation und Technologie – BMVIT)  Radetzkystrasse 2, 1030 Vienna, Austria Telephone: +43 1 711 65 2306 (direct dial) Email: sch3@bmvit.gv.at
Market surveillance authority	Federal Minister of Transport, Innovation and Technology (BMVIT)  Provincial authority with local jurisdiction

### Basic strategy

A material aim of the Cableways Directive is to facilitate the free trade of safety components and subsystems. This Directive is therefore organised in line with the new approach of technical standardisation. This new approach specifies basic requirements that serve to ensure a high level of safety.

The national authorities are responsible for ensuring that the basic requirements are met.

The marketer of subsystems and safety components and the notified bodies are responsible for assessing and confirming that these products conform with the basic requirements. Together with the declaration of conformity and verification of the intended use of these parts in a specific system, the cableway manufacturer must provide the required proof of safety to be granted an operating licence from the competent authorities (provisional governors on behalf of the Federal Minister of Transport, Innovation and Technology).

### Criteria for the selection of products

Subsystems and safety components in the context of approval processes; reviews of priorities on the basis of RAPEX and ICSMS notifications

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## **Cooperation with other authorities**

Upon request, collaboration with the Federal Ministry of Science, Research and Economy (BMWFW)

## **Where surveillance takes place**

Nationwide; at the operator

## **Forms of surveillance**

Surveillance of safety components or subsystems is carried out as part of the building permit process or operating licence process and as part of recurring reviews (SeilbÜV) and reviews of priorities

## **Product groups scheduled for surveillance**

Subsystems and safety components of cableway systems.



## 6.28 Toys

EU legal provisions	Directive 2009/48/EC on the safety of toys
Transposition in Austria	<p>Toys Regulation (Spielzeugverordnung), BGBl II No 203/2011</p> <p>Toys (Labelling) Regulation (Spielzeugkennzeichnungsverordnung), BGBl No 1994/1029</p> <p>Regulation on Gaseous Inflatants for Toy Balloons (Verordnung über gasförmige Füllstoffe für Spielzeugluftballons), BGBl No 1978/22</p> <p>Lebensmittelsicherheits- und Verbraucherschutzgesetz (Food Safety and Consumer Protection Act) BGBl. I No 13/2006, as amended</p>
Competent federal authority	<p>Federal Ministry of Health (Bundesministerium für Gesundheit – BMG), Division II/B/14</p> <p>Radetzkystrasse 2, 1030 Vienna, Austria</p> <p>Telephone: +43 1/711 00 4872 (direct dial)</p> <p>Email: IIB14@bmg.gv.at</p>
Market surveillance authority	Provincial authority with local jurisdiction

### Basic strategy

Toys within the meaning of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ('Toys Directive') are covered by the national control plan (audit and sampling plan) and have long been subject to the legal framework established by the Food Safety and Consumer Protection Act. Accordingly, surveillance of toys, like that of other relevant product groups, is carried out by the competent food inspectorates of the provinces. In this area too, annual targeted actions are normally scheduled; these are prescribed in detail by the Federal Ministry of Health by means of a general circular.

### Criteria for the selection of products

Risk-based surveillance and monitoring to maintain an overview of the market, possibly European Commission requirements in some cases and selection based on RAPEX notifications (targeted actions).

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## **Cooperation with other authorities**

Cooperation may take place with the customs authorities on request.

## **Where surveillance takes place**

Surveillance takes place nationwide; in retail outlets, wholesale warehouses and manufacturing facilities and in the context of import controls.

## **Forms of surveillance**

Surveillance of toys is carried out in the framework of the national control plan (audit and sampling plan), the focal points of which generally change from year to year. The emphasis is on proactive planning of market surveillance in the form of sampling plans, reactive surveillance in the form of checks on suspect samples and proactive/reactive surveillance in the form of targeted actions.

## **Product groups scheduled for surveillance**

Controls in the form of the usual spot checks that can be carried out at any time will focus on the following in 2016: Low-cost toys (from fairs and similar); the safety of toy scooters and toy buggies, toys with lasers and the safety of fluffy balls.

## 6.29 Recreational craft

EU legal provisions	Directive 94/25/EC Directive 2003/44/EC amending Directive 94/25/EC from 18/01/2016: Directive 2013/53/EU
Transposition in Austria	Recreational Craft (Requirements) Regulation (Verordnung über Anforderungen an Sportboote), BGBl. II No 276/2004, last amended by BGBl. II No 9/2007 from 18/01/2016: Recreational Craft Regulation 2015 – SpBV 2015
Competent federal authority	Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Division I/9  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 8225 (direct dial) Email: post.I9@bmwfw.gv.at
Market surveillance authority	District administrative authority with local jurisdiction

### Basic strategy

Reactive surveillance is exercised on an ad hoc basis in response to accidents and complaints (e.g. from users) and in response to notifications from other Member States and the European Commission through the CIRCABC, ICSMS and RAPEX systems.

Proactive market surveillance is carried out in the context of motor boat licensing, which requires conformity with the guidelines. In addition, checks are carried out at trade fairs and participation in European market surveillance campaigns initiated by the RCD Administrative Cooperation (ADCO) group is planned.

### Criteria for the selection of products

In the event of European market surveillance campaigns, the products to be subjected to surveillance are determined by the given project. Otherwise controls are carried out in accordance with the principles of risk assessment.

### Cooperation with other authorities

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Within Austria, cooperation takes place on an ad hoc basis with the customs authorities, which are part of the Federal Ministry of Finance, and with the Federal Ministry of Labour, Social Affairs and Consumer Protection, which is responsible for the application of Directive 2001/95/EC on general product safety. In the EU context, cooperation takes place with the market surveillance authorities of the other Member States.

### **Where surveillance takes place**

Surveillance takes place primarily at trade fairs. Motorised craft need to be registered by the provincial authorities; during that process, compliance with the requirements of the Directive is verified.

### **Forms of surveillance**

Market surveillance is carried out locally by the supervisory authority of first instance, chiefly by means of visual inspection and perusal of the available documentation relating to the placing on the market of the relevant products (declarations of conformity and operating instructions). The authorities also discharge their responsibilities by performing spot checks. When appliances are imported into Austria from non-EU countries, products are inspected jointly with the customs authorities.

### **Product groups scheduled for surveillance**

The selection of product groups for surveillance is based, in principle, on the ADCO programmes. No such programme is planned for 2016.

## 6.30 Explosives

EU legal provisions	Directive 93/15/EEC
Transposition in Austria	Explosives Act (Sprengmittelgesetz) 2010, BGBl. I No 121/2009
Competent federal authority	Federal Ministry of the Interior (Bundesministerium für Inneres – BM.I)  1010 Vienna, Herrengasse 7 Tel. Email: BMI-III-3@bmi.gv.at
Market surveillance authority	Provincial police headquarters with local jurisdiction: Vienna Provincial Police Headquarters (Landespolizeidirektion Wien) Schottenring 7–9, 1010 Vienna, Austria Telephone: +43 (1) 31310-0 Email: LPD-W@polizei.gv.at  Lower Austria Provincial Police Headquarters (Landespolizeidirektion Niederösterreich) Neue Herrengasse 15, 3100 St. Pölten, Austria Telephone: +43 059133 30-0 Fax: +43 059133 30-1009 Email: LPD-N@polizei.gv.at  Upper Austria Provincial Police Headquarters (Landespolizeidirektion Oberösterreich) Gruberstrasse 35, 4021 Linz, Austria Telephone: +43 059133 40-0 Fax: +43 059133 30-1009 Email: LPD-O@polizei.gv.at  Salzburg Provincial Police Headquarters (Landespolizeidirektion Salzburg) Alpenstrasse 90, 5020 Salzburg, Austria Telephone: +43 059133 50-0 Fax: +43 059133 50-1009 Email: LPD-S@polizei.gv.at  Tyrol Provincial Police Headquarters (Landespolizeidirektion Tirol)

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## Basic strategy

The Explosives Act 2010 provides for both reactive and proactive market surveillance measures.

## Criteria for the selection of products

The selection of products is guided by the explosives that are being purchased in the market and by reports of any defective products.

## Cooperation with other authorities

Provision is made in the Explosives Act for cooperation with the customs authorities.

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## **Where surveillance takes place**

Surveillance activities are essentially focused on storage facilities for explosives.

## **Forms of surveillance**

Visual checks on the serviceability of ammunition and explosives are chiefly supplemented by perusal of business documentation and directories.

## **Product groups scheduled for surveillance**

No specific surveillance of particular product groups is planned for 2016. Surveillance will continue to be exercised in the context of the statutory inspections of storage facilities and in response to relevant information from the market.

## 6.31 Product safety for consumers

EU legal provisions	Directive 2001/95/EC on general product safety
Transposition in Austria	Product Safety Act (Produktsicherheitsgesetz – PSG) 2004, BGBl. I No 16/2005
Competent federal authority	Federal Ministry of Labour, Social Affairs and Consumer Protection (Bundesministerium für Arbeit, Soziales und Konsumentenschutz), Division III/2 (also national RAPEX contact point)  Stubenring 1, 1011 Vienna, Austria Tel. +43 1 711 00 2511 (direct dial) Email: produktsicherheit@sozialministerium.at
Market surveillance authority	Provincial government authorities

### General

The Product Safety Act 2004 applies in principle to all consumer goods for which there are either no specific statutory instruments or specific instruments that do not lay down such high safety standards as the Product Safety Act. In other words, the Product Safety Act is subsidiary to specific legislative instruments, which take precedence in principle.

Product groups that are always governed by the Product Safety Act include furniture, sports requisites, tools, textiles, decorative items, leisure equipment and children's articles, but not products such as toys, personal protective equipment, electrical appliances and machinery, which are covered by separate statutory instruments.

For products covered by the Product Safety Act, there is no provision for 'CE' marking, which means that such marking of these products is not permissible.

### Basic strategy

Market surveillance is exercised on a reactive basis, on the one hand, mainly in the form of market investigations in response to notifications from RAPEX, the Community Rapid Information System on product safety. In addition, ad hoc investigations are conducted in the wake of accidents, consumer complaints, notifications from hospitals or the executive, and media reports.

The market is also monitored actively, which involves not only the definition of annual surveillance priorities in consultation with the monitoring provinces but also general surveillance of the range of marketed goods.

Product samples are taken on behalf of the Federal Ministry of Labour, Social

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Affairs and Consumer Protection by external test institutes. In the event of imminent danger, emergency measures are taken by the surveillance authorities for product safety; measures with long-term effects (ministerial decisions and regulations) are a matter for the Federal Ministry.

### **Criteria for the selection of products**

Besides the requirements deriving from reactive market surveillance — responding to RAPEX notifications, etc. — product groups are selected for special surveillance on the basis of past accidents (e.g. accident statistics) and of risk. Part of the selection process is also determined by international projects, such as PROSAFE Joint Market Surveillance Actions.

### **Cooperation with other authorities**

Under the Product Safety Act 2004, the Federal Ministry of Labour, Social Affairs and Consumer Protection has an obligation to coordinate and train the competent market surveillance authorities and bodies. It meets this obligation by holding regular coordination meetings with the provincial authorities, and training courses for product safety enforcement bodies (sometimes project-related and national).

The Advisory Council on Product Safety (Produktsicherheitsbeirat), which includes representatives of other federal ministries and of the provincial authorities, also performs a coordinating function.

International cooperation in the field of market surveillance takes place primarily in the Consumer Safety Network of the European Commission, focusing to an increasing extent on projects organised by PROSAFE with support from the European Commission. Individual provinces are also engaged in cooperative ventures with neighbouring EU Member States.

### **Where surveillance takes place**

The main focal point of surveillance activity is retail trade, although there are plans to shift the focus towards wholesalers, importers and manufacturers. In addition, cooperation with the customs service has been intensified over the past few years. Distance selling (online trade) is also monitored.

### **Forms of surveillance**

Surveillance generally comprises on-site visual inspections, sampling and laboratory tests.

### **Product groups scheduled for surveillance**

For 2016, besides the routine surveillance activities, it is planned to subject the following items inter alia to particular scrutiny:

- Scooters for adults

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- Baby walking frames
- Fire extinguishers (functional tests)
- CO detectors