

LAST NEWS ON SPC in EU countries

Medicinal and Plant Protection SPCs in Europe

About 8320 SPC applications have been filed in Europe from January 1991 to December 2003:

- about 7510 for medicinal products regulated by EC Regulation 1768/92 or National laws
- about 810 for plant protection products regulated by EC Regulation 1610/96 or National laws.

EU SPC Regulation entered in force in the ten new EU countries on 1st May 2004 but except in Hungary and Poland there were already SPC provisions in national patent laws. About 180 filed SPCs have been granted and/or published (Cyprus, 78; Czech Republic, 51; Estonia, 4; Lithuania, 6; Latvia, 8; Slovenia, 12; Slovakia, 24; no data for Malta).

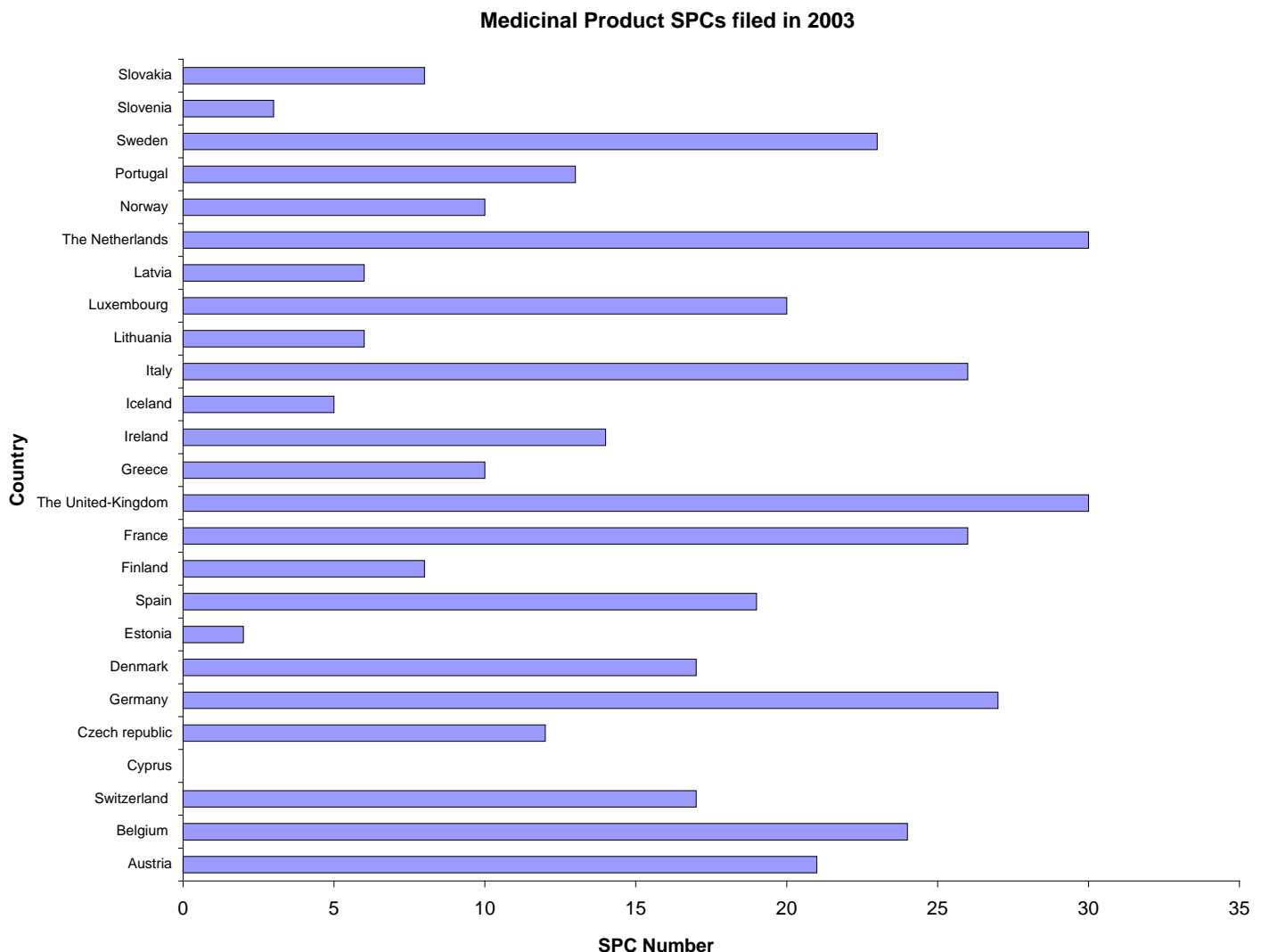
➤ **MEDICINAL PRODUCT SPCS IN EUROPE**

❖ **Medicinal Product SPCs in Europe in 2003**

How many SPCs?

377 SPCs filed in 2003 were published at the end of May 2004.

The figure below represents the number of SPCs sorted by country.



Which medicinal products?

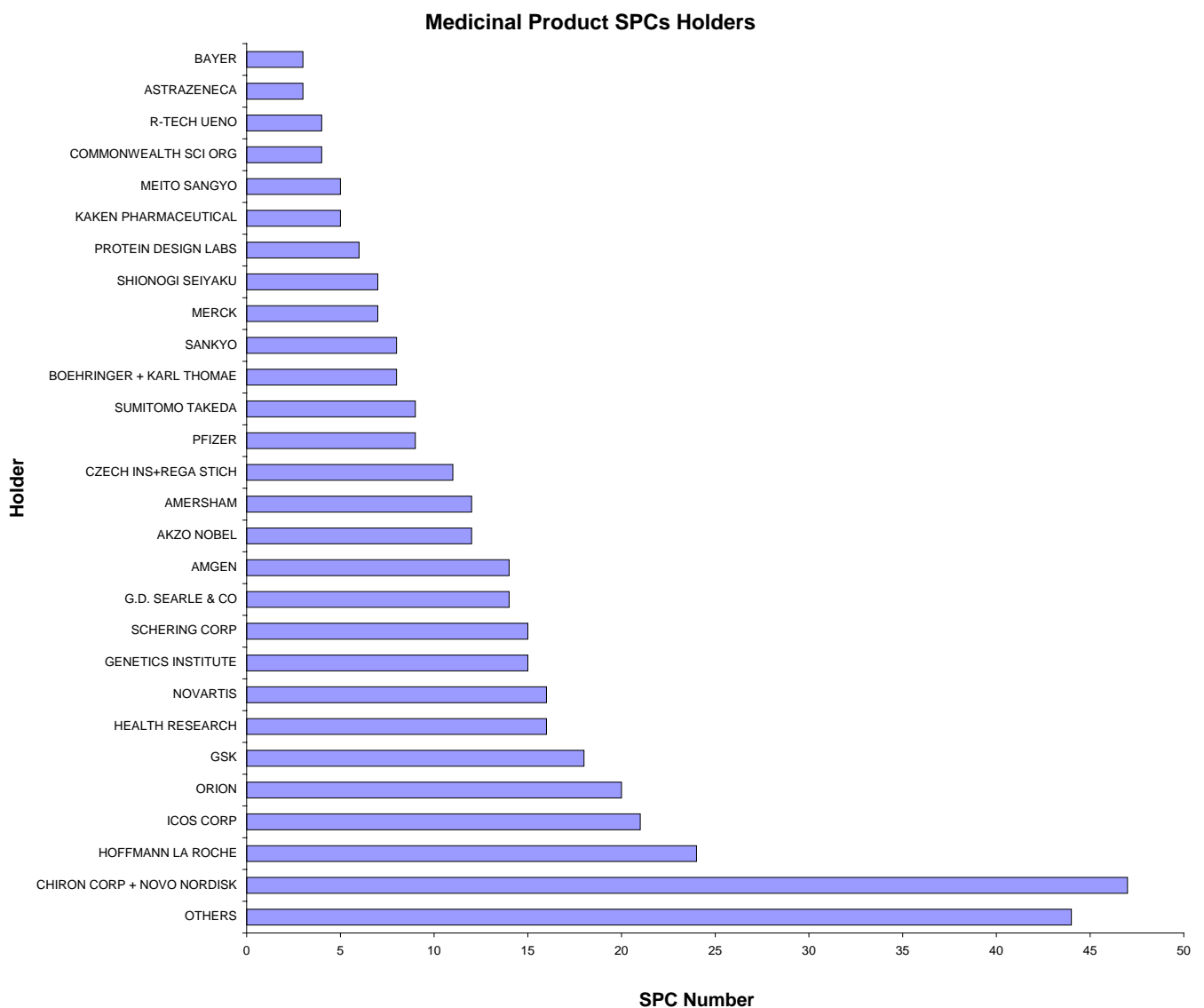
The 377 SPCs, filed in 2003 and published, cover about 84 different products (active ingredients, combinations of active ingredients, or formulations).

The 84 different products can be roughly sorted according to their therapeutic category:

- **Cardiology, haematology:** 13
- **Neurology:** 12
- **Anti-infectives:** 10
- **Immunosuppressive, Immunomodulator:** 10
- **Hormones, osteoporosis:** 7
- **Vaccines:** 6
- **Anti-inflammatory:** 6
- **Diagnostic:** 5
- **Metabolism:** 4
- **Other:** 11.

Who filed Medicinal product SPCs and for which products?

The figure below represents the number of SPCs sorted by holder.



We can note for the main first holders:

CHIRON CORP + NOVO NORDISK

- Enfuvirtide:

SPCs in AT, BE, DE, FR, GB, IT, LU, NL, SE, referring to 1985 **Chiron** patent and to April 2003 Swiss MA or to May 2003 EU MA, with an extension of five years.

- Moroctocog alfa:

SPCs in AT, BE, DE, FR, GB, IT, LU, NL, SE, referring to 1985 **Chiron/Novo Nordisk** patent and to April 1999 EU MA with an extension of 5 years.

Other SPCs filed in 1999 for moroctocog alfa in AT, BE, DE, DK, FR, GB, IT, LU, NL, SE, referring to the same MA and to 1986 **Genetics Institute** patent and in AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, NL, SE, referring to the same MA (or to Swiss MA for Switzerland) and to 1990 **Biovitrum or Pharmacia & Upjohn** patent.

- Octocog alfa:

SPCs in AT, BE, CH, DE, GB, IT, LU, NL, SE, referring to **Chiron/Novo Nordisk** 1985 patent and to April 1994 Dutch MA or April 2000 EU MA with an extension of about 3 years 5 months or an extension of 5 years.

Other SPCs for octocog alfa: SPCs filed in 1993 or 1994 in BE, DE, FR, GB, LU, NL, SE referring, to 1982 **Scripps Research** patent and to November 1989 Luxembourg MA, SPCs filed in 1997 in AT referring to 1984 **Genetics Institute** patent and to 1992 Swedish MA or 1993 Dutch MA, SPCs filed in 1994 or 1995 in AT, DE, DK, FR, GB, IE, LU, NL, SE referring to 1985 **Genentech** patent and to 1994 Dutch MA and SPCs filed in 1995 in FR referring to 1988 or 1989 CRTS Lille patents and to 1994 French MA.

- Rurioctocog alfa:

SPCs referring to 1985 **Chiron/Novo Nordisk** patent and to December 1992 Swedish MA in AT, BE, CH, DE, GB, IT, LU, NL, SE with an extension of about 2 years 11 months, or to May 1993 Dutch MA in IT with extension of about 3 years 4 months or to September 1993 EU MA in LU with extension of about 3 years 8 months or to January 1996 Swiss MA in CH with extension of 5 years.

- Somatropin or combination of somatropin and histidine:

SPCs in CH, DE, DK, ES, FR, GB, IE, IT, NL, SE, referring to 1992 **Novo Nordisk** patent and to March 1999 Danish MA with an extension of about 1 year 3 months or to June 1999 Swiss MA (extension of about 1 year 6 months).

HOFFMANN LA ROCHE

- Etanercept:

SPCs in AT, BE, CH, DE, FR, GB, IT, NL, referring to 1990 patent and to 1st February 2000 EU MA or 3rd February 2000 Swiss MA with an extension of about 4 years 5 months.

Other SPCs for etanercept, referring to the same MAs: SPC filed in 2000 referring to 1991 **Hoechst** patent or to 1990 **Imunex Corporation** patent or to 1990 **BASF** patent.

- Peginterferon alfa 2a:

SPCs in BE, DE, ES, FR, GB, IE, IT, LT, LU, LV, NL, SE, SI, referring to 1997 patent and to June 2002 EU or 2001 or 2002 National MAs with an extension of about 1 month in BE, DE, FR, IE, NL, SE, 4,5 months in LV, 5,5 months in LT, no extension in GB (SPC for peginterferon alfa 2a filed in CH in 2001 referring to 1996 patent was withdrawn).

- Valganciclovir or valganciclovir hydrochloride:

SPCs in CZ, FR, NO referring to 1995 patent and to September 2001 NL MA or to CZ MA with an extension of about 1 year 2 months or 2 years 8 months (corresponding SPCs were filed in 2001 or 2002 in AT, BE, DE, DK, ES, GB, GR, IE, NL, PT, SE).

ICOS CORP

- Tadalafil:

SPCs in 22 countries referring to 1995 patent and to November 2002 EU MA or 2002 or 2003 National MAs with an extension of more than 3 years (EE, LT, LV, SI), 3 years (CZ), 2 years 11 months (SK) or 2 years 10 months (AT, BE, DE, ES, FI, FR, GB, GR, IE, IS, IT, LU, NL, NO, PT, SE).

ORION

- Dexmedetomidine or Dexmedetomidine hydrochloride:

SPCs in AT, BE, DE, DK, ES, FI, FR, GB, IE, IT, LU, NL, NO, PT, SE, referring to 1988 patent and to August 2002 EU MA with an extension of 5 years.

- Entacapone:

SPC in NL referring to NL patent and to September 1998 EU MA with an extension of 5 years (corresponding SPCs were filed in 1999 in AT, BE, CH, DE, ES, FI, FR, GB, GR, IE, IT, LU, NL, NO, PT, SE).

- Levosimendan:

- SPCs in CZ, IT, SK, referring to 1990 patent and to September 2000 SE MA or 2002 National MA with an extension of 5 years (corresponding SPCs were filed in 2001 or 2002 in AT, FI, GR, LU, NO, PT, SE);

- SPCs in IT, SK, referring to 1992 patent and to the same MAs with an extension of about 3 years 8 months (corresponding SPCs were filed in 2001 or 2002 in AT, FI, GR, LU, NO, SE).

GSK

- Combination of amoxicillin and potassium clavulanate:

2 SPCs in BE, referring to a 1984 **Beecham** patent or to a 1995 **SmithklineBeecham** patent and to a October 2002 BE MA with extension of 5 years and about 2 years 8 months, respectively.

- Dutasteride:

SPCs in 15 countries, referring to 1994 **SmithklineBeecham** patent and to July 2002 SE MA or 2003 national MAs with an extension of about 4 years in CZ, LT, about 3 years 4 months (CH) or 2 years 10 months (BE, DE, DK, ES, FR, GB, GR, IS, NL, NO, PT, SE).

- Combination of eprosartan and hydrochlorothiazide:

SPCs in NL, DE, referring to 1991 **SmithklineBeecham** patent and to 2002 national MAs with an extension of 5 years.

- Ropinirole or ropinirole hydrochloride:

SPC in FI, referring to 1983 **SmithklineBeecham** patent and to July 1996 UK MA with an extension of 5 years (corresponding SPCs were filed in 1996 or 1997 in AT, BE, CH, DE, DK, GB, IE, IT, LU, NL, NO, SE); other SPCs referring to 1988 or 1991 **SmithklineBeecham** patents in AT, BE, CH, DE, DK, GB, IE, IT, LU, NL, NO, SE).

- Valganciclovir or valganciclovir hydrochloride:

SPCs in FR, IT, referring to **Wellcome** 1989 patent and to September 2001 NL MA with an extension of 5 years (corresponding SPCs filed in 2002 in AT, CH, DE, GB, IT).

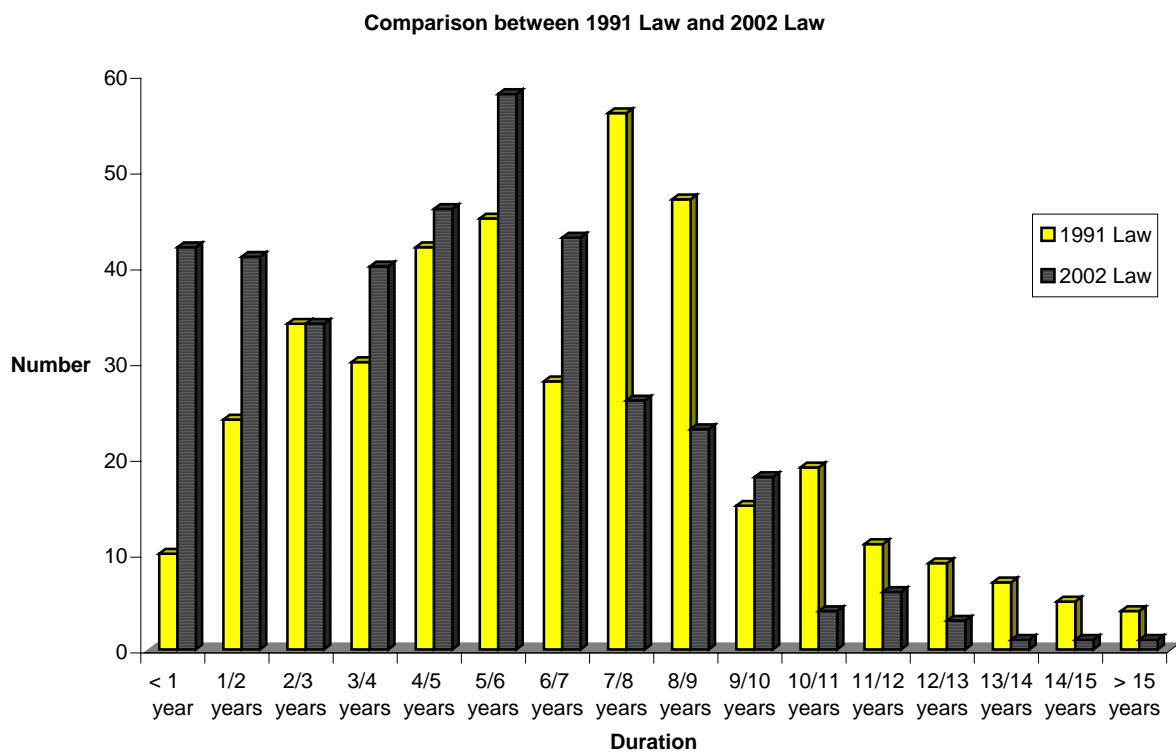
❖ Italian National SPCs

Italian National SPCs are regulated by Italian Law 1991/349 modified by Italian Law 2001/112 which entered in force on 1 January 2004. According to this law the SPC duration is reduced by 6 months every year. If the expiry for the related year is between July and December of the previous year the expiry will be in any case on 31 December of this previous year.

About 390 SPCs have been granted and about 340 were still in force on 1 January 2004. The SPC average duration according to the new law is 4.8 years instead of 6.43 years according to 349 law.

The figure below represents the number of SPCs sorted by duration according to:

- Former Law 1991/349
- Law 2001/112



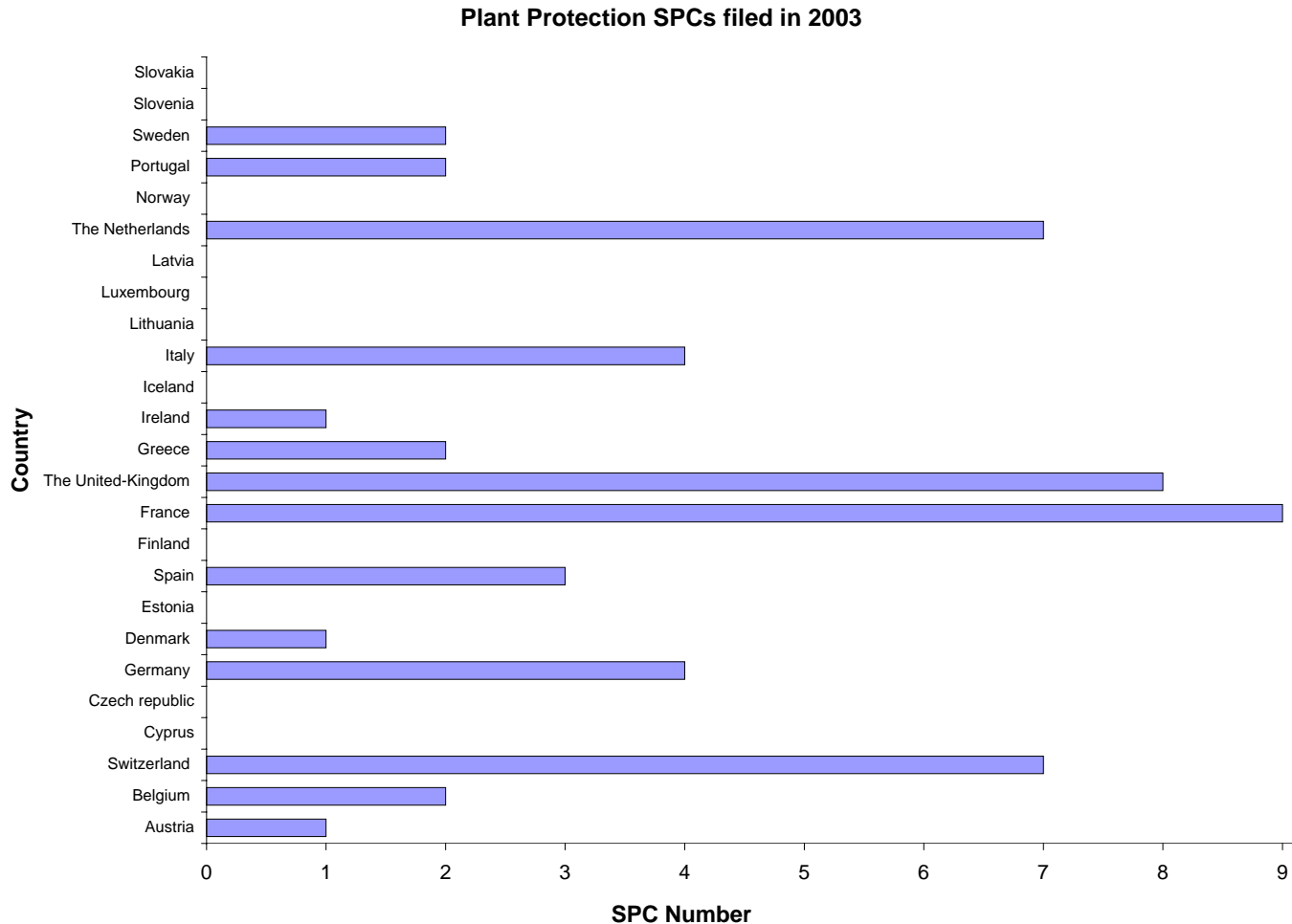
➤ PLANT PROTECTION SPCS IN EUROPE

❖ Plant Protection Product SPCs in 2003

How many SPCs?

53 SPCs filed in 2003 were published at the end of May 2004.

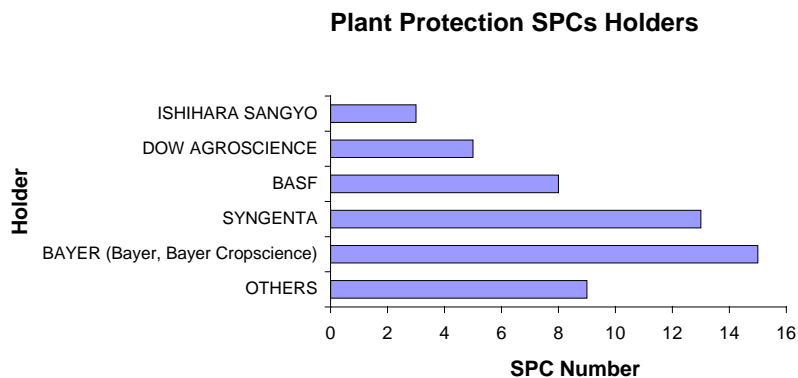
The figure below represents the number of SPCs sorted by country.



We can rank countries by number of SPCs, which are an indication of the importance of the market:

- more than 7 SPCs: The Netherlands, Switzerland, The United-Kingdom and France
- 3 or 4 SPCs: Spain, Germany and Italy.

Who filed Plant Protection SPCs?



We noted that European firms represent about 75% of the applicants, the Japanese and the American ones, each about 13%.