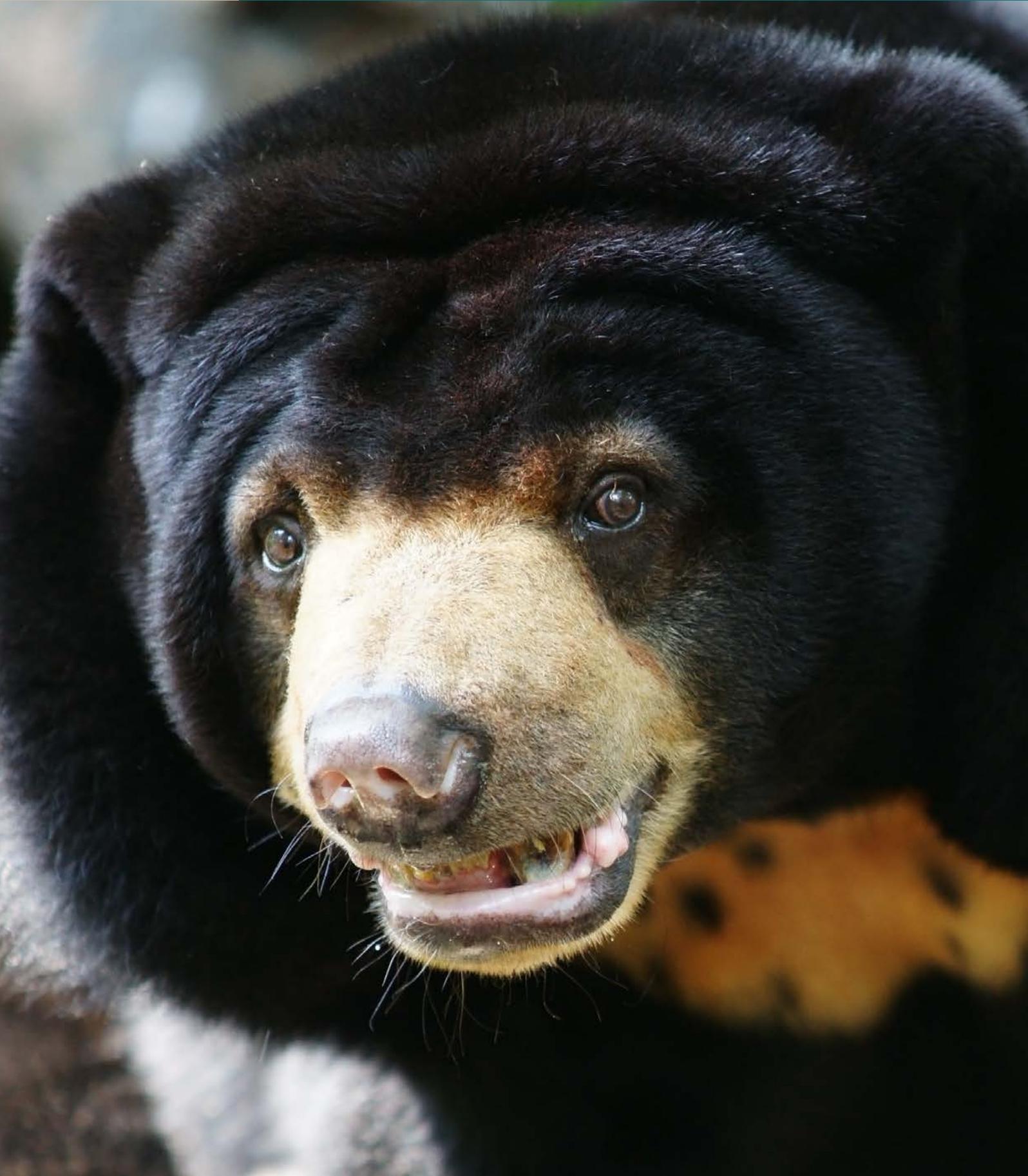


HARD TO BEAR:

An assessment of trade in bear bile and gall bladder in Malaysia

Lee Siow Ling, Elizabeth A. Burgess and Serene C.L. Chng





TRAFFIC REPORT

TRAFFIC, the wildlife trade monitoring network, is the leading non-governmental organization working globally on trade in wild animals and plants in the context of both biodiversity conservation and sustainable development. TRAFFIC is a strategic alliance of WWF and IUCN.

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Selangor, Malaysia
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Fax: (603) 7882 0171

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*Lee Siow Ling, Elizabeth A. Burgess
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Bear bile flakes in vials for sale in a TCM shop.

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ABBREVIATIONS AND ACRONYMS

ASEAN	Association of Southeast Asian Nations
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CLAW	Cancellation of Licences in Aid of Wildlife
DRGD	Drug Registration Guidance Document
DWNP	Department of Wildlife and National Parks, Malaysia
GMP	Good Manufacturing Practice
IUCN	International Union for Conservation of Nature
MOH	Ministry of Health, Malaysia
MNRE	Ministry of Natural Resources and Environment, Malaysia
MYCAT	Malaysian Conservation Alliance for Tigers
MYR	Malaysian Ringgit
NPCB	National Pharmaceutical Control Bureau
SFC	Sarawak Forest Corporation
SFD	Sarawak Forestry Department
SWD	Sabah Wildlife Department
TCM	Traditional Chinese Medicine
UDCA	Ursodeoxycholic Acid
USD	US Dollar

EXECUTIVE SUMMARY

The Asiatic Black Bear *Ursus thibetanus* and the Sun Bear *Helarctos malayanus* are under threat from the illegal trade in traditional Chinese medicines (TCM) containing bear bile and gall bladder. This study reports on a 2012 survey of the trade in bear parts and derivatives in 365 TCM shops throughout all 13 states of Malaysia and the Federal Territory of Kuala Lumpur.

Almost half of TCM shops (48%) openly claimed to be selling and/or displayed authentic bear gall bladder and/or bile. The greatest proportion was found in Peninsular Malaysia compared to Sabah and Sarawak, and the States of Kelantan and Johor had the highest proportion of shops selling bear gall bladder and/or bile products. Of those shops selling bear products, the majority (>80%) claimed to have ongoing supplies of at least some of the items. Over a third of all shops surveyed (37%) claimed to have no bear products for sale, although the majority of these offered supposed 'herbal' *Xiongdan* (bear bile) pills. There appears to be a lack of clear labelling of products, perhaps deliberately in order to circumvent the law. Traders may also be unwilling to reveal product provenance to an unknown customer, resulting in possibly under-reported sales of bear products.

Bear parts and products found to be available in Malaysia were whole gall bladders, bile pills, bile extract or powder, flakes and dried gall bladder skin, among other derivatives. Pills were the most common item, particularly in Peninsular Malaysia, and most were reported to be locally manufactured, though using imported ingredients. Whole gall bladders were the second most common item observed, but predominantly in Sabah and Sarawak. Nearly 60% of all bear gall bladders observed for retail were claimed to be sourced from Sun Bears killed locally by indigenous people.

Staff in more than half of shops surveyed were aware of the illegal nature of the trade in bear parts and products. Since a similar survey of bear product availability in TCM shops carried out by TRAFFIC in 2010 in Malaysia, there appears to have been a small (10%) reduction in the number of shops that claimed to offer bear products. This could partly be a result the new Wildlife Conservation Act 2010 coming into force and the subsequent notification by the Department of Wildlife and National Parks (DWNP) to TCM practitioners. However, shop owners felt that there was little risk from enforcement efforts, some even alleging corruption among enforcement officers.

Despite largely adequate legislation in Malaysia, there is still a significant way to go to stamp out the illegal trade in bear parts and products within the country. Insufficient scrutiny has resulted in the Ministry of Health (MOH) unwittingly approving some TCM products containing bear derivatives. This contradicts prohibition under wildlife laws and creates confusion as well as a sense that existing laws cannot be enforced. MOH has since taken actions towards ensuring that locally made and imported medicines containing bear products are not registered for legal sale in the country.

Recommendations

Survey results have pointed to a number of areas where improvements could greatly enhance the effective control of trade involving bear parts and products:

Legal and Policy Framework

- Consistency in legislation is recommended to ensure that all trade in bear parts and derivatives is effectively banned within Malaysia. This has already been addressed in wildlife laws. However, the *Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984)* should specifically include a clause ensuring that domestic and imported traditional medicines containing wildlife derivatives must adhere to wildlife regulations before being awarded Good Manufacturing Practice certification (which is mandatory for a manufacturing licence and product registration, and is applicable to importers and wholesalers as well as manufacturers), issued permits for sale of medicine, and/or granted product trade and consumption approvals.
- Sun Bears in Sarawak should be accorded the highest level of protection and listed as ‘Totally Protected’ under the *Sarawak Wildlife Protection Ordinance 1998*. This would result in higher penalties for offenders, creating greater deterrent effect, as well as stronger formal protection.
- MOH is recommended to recognise that some traditional medicine is prescribed in its raw form, which excludes them from enforcement under the *Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984)* although they are sold as a medicine. TRAFFIC recommends that MOH and the Ministry of Natural Resources and Environment (MNRE) address this jointly.
- In Selangor, business permits of retailers found to be repeatedly flouting the *Wildlife Conservation Act 2010* and the *International Trade in Endangered Species Act 2008* by selling wildlife illegally or products containing wildlife parts can be suspended under the state government’s Cancellation of Licences in Aid of Wildlife (CLAW) programme. This novel programme is intended to aid both federal and state law enforcement agencies stop illegal wildlife trade and presents a strong deterrent effect, and should be considered by other states too.

Enforcement

- MOH is urged to improve the screening process when registering medicinal products containing animal derivatives. It is recommended that MOH’s pharmaceutical enforcement department be more vigilant when carrying out inspections and raids, for instance searching for products in Chinese language as a number of products are imported from China.
- Individuals and companies importing, collecting, selling, buying, transporting or keeping bear parts and derivatives are in violation of CITES and/or national laws (*Wildlife Conservation Act 2010, Sarawak Wildlife Protection Ordinance 1998, Sabah Wildlife Conservation Enactment 1997, International Trade in Endangered Species Act 2008*) and must be prosecuted and penalized to act as a deterrent and to demonstrate the Government’s commitment to stopping the illegal trade in endangered animals such as bears. Claiming that manufactured products contain bear bile, regardless of the actual contents, is also an offence under the *Wildlife Conservation Act 2010*.
- Collaboration between wildlife departments, the MOH pharmaceutical enforcement units and city council law enforcement units to carry out concerted and frequent checks and raids on TCM shops are required. Given the vast number of TCM practitioners throughout the country and differing jurisdictions, this approach capitalises on limited resources, enable unregistered medications containing protected wildlife, and wildlife parts in their raw form to be confiscated and offending businesses to be charged in court. This will also improve enforcement efforts at a local level and strengthen the message that selling illegal wildlife products is a serious offence considered by all arms of the Malaysian government.

- As TCM shops surveyed in the two East Malaysian states of Sabah and Sarawak that sold gall bladders sourced them from native Sun Bears, concerted enforcement efforts by the Sabah Wildlife Department and Sarawak Forest Corporation are needed to combat the poaching and trade of Sun Bears on Malaysian Borneo, and to prevent the illegal sourcing of bear parts by poachers to the TCM industry.
- MOH is urged to check on factories manufacturing Chinese medicines in Malaysia to ensure that legal standards are adhered to in the import of raw materials for the production of TCM products containing wildlife. More thorough background checks on such operations are recommended before they are granted manufacturing licences by MOH.
- MOH is urged to develop and implement a formal mechanism to regulate the dispensing activities of TCM medicine retailers, as these are currently not covered under existing legislations.

Co-ordination

- Closer co-operation is encouraged between government departments dealing with wildlife and health issues to promote efficiency in efforts to combat illegal trade in bear parts, derivatives and products. These should include the Department of Wildlife and National Parks, Sabah Wildlife Department, Sarawak Forest Department, Sarawak Forestry Corporation, the Traditional and Complementary Medicine Unit and the National Pharmaceutical Control Bureau of MOH, the Customs Department and local governments.
- Relevant government departments should form strategic alliances with NGOs, universities and other research centres to carry out monitoring, research and education efforts conducive to effective implementation of wildlife laws, including but not restricted to the testing of contents of *Xiongdan* pills and other products alleged to contain bear bile.
- Dialogue should be encouraged between government, NGO and TCM communities on issues of bear use in TCM, through forums such as the International Conference in Traditional Chinese Medicine.

Purchasing

- Wide-scale and sustained public education campaigns should be promoted to highlight issues of bear bile trade in TCM and to engage the public in responsible and legal purchasing of TCM products. The conservation and judicial consequences of purchasing bear products should be made clear.
- TCM practitioners and retailers should be encouraged to promote the use of herbal alternatives to bear products and advise consumers how to avoid using bear gall bladder, bile and products and why. The Federation of Chinese Physicians and Medicine Dealers Association of Malaysia is also urged to take a stance in opposing the use of bear parts and products in TCM.

执行摘要

亚洲黑熊 *Ursus thibetanus* 和马来熊 *Helarctos malayanus* 正遭受着传统中医药 (TCM) 里非法熊胆汁和胆囊贸易的威胁。这份研究报告是关于2012年在马来西亚全部13个州和吉隆坡联邦直辖区里的365家中药店所进行的熊个体和其制品贸易的一项调查。

几乎有一半的中药店 (48%) 公开声称有出售和/或展示熊胆和胆汁。马来西亚半岛 (相对于沙巴和砂劳越) 占了最大比例。其中在吉兰丹州和柔佛州出售熊胆和胆汁产品的中药店占中药店总量的比例最大。这些出售熊产品的商店中, 绝大部分 (超过 80%) 声称至少一样产品货源充足。调查里的商店中, 超过三分之一 (37%) 声称没有熊产品可供出售, 但他们绝大多数都在销售名为“熊胆”的“草药”药丸。这些产品并没有明确的标签, 可能是为了刻意回避法律制裁。贸易商也不愿意向陌生客户透露产品的出处。上述可能是造成熊产品销售并未时常见诸报端的原因。

在马来西亚被发现出售的熊产品为: 胆囊整体、胆汁丸、胆汁提取物或粉末、胆片、干胆皮和其他衍生物。胆丸是最常见的物品, 特别是在马来西亚半岛, 尽管原料多为进口, 大多数药丸还是在当地进行加工制作。完整的胆囊整体是第二常见的物品, 主要在沙巴和砂劳越销售。零售的胆囊, 据称有近60%来自于当地杀害的马来熊。

超过一半的受调查商店工作人员知道熊产品贸易是非法的。自从2010年TRAFFIC在马来西亚进行一个类似的中药店熊产品销售的调查之后, 新出台了一项《2010年野生动物保育法》, 随后野生动物与国家公园部门 (DWNP) 发表了声明。以上新措施颁布之后, 提供熊产品的商店稍微减少了 (10%)。然而, 一些商家对于执法行动不屑一顾, 有人甚至提出质疑, 认为执法人员中存在腐败现象。

尽管马来西亚拥有相较为善的法律, 但要杜绝国内熊产品非法贸易仍有很长的路要走。由于审查不到位导致卫生部门 (MOH) 在不知情的情况下批准了一些含有熊衍生物的中药产品。这违反了野生动物保护法, 导致混着, 并让人们以为现行法律无法顺利开展。此后, 卫生部已采取行动, 确保该国不会注册含有熊产品成分的国产和进口药物为合法销售物。

建议

调查结果显示, 只要对下述方面进行改善, 就能大幅度提高对熊产品贸易的有效控制:

法律和政策框架

- 马来西亚政府应继续加强中药行业中有关禁止熊胆贸易相关的立法, 确保所有熊产品及其衍生物贸易在马来西亚境内能够被有效地被禁止。野生动物法律已经涵盖了这个课题。建议卫生部在《1952年药品销售法 (1984年药品和化妆品监管管制)》加入条文, 规定含有野生动物衍生品的国产与进口传统药物必须符合野生动物保护条例 (明确来说是《2010年野生动物保育法》和《2008年濒危物种国际贸易法》), 方可颁发生产许可 (这是生产许可证和商品注册的强制性文件, 并适用于进口商、批发商以及制造商), 签发药物售卖许可证以及批准产品的交易和买卖。
- 砂劳越的马来熊应受到最高的法律保护, 并将其列入《1998年砂劳越野生动物保护条例》中‘完全受保护’级别。违法者将面临更严厉的惩罚, 以儆效尤, 以此提高对马来熊的保护力度。
- 建议卫生部门需判别出有些传统药物是以原材料形式配发的, 并因此被排除在《1952年药物销售法 (1984年药品和化妆品监管管制)》的执法范围里, 纵使它们是以药物来出售。TRAFFIC建议, 卫生部和自然资源和环境部 (MNRE) 共同解决这个问题。
- 在雪兰莪州, 零售商若被发现一再违反《2010年野生动物保育法》和《2008年濒危物种国际贸易法》, 非法出售野生动物及其制品, 其营业执照将按照州政府颁布的“非法出售野生动物制品吊销营业执照行动 (CLAW)”被吊销。这项新举措是为了帮助联邦和州执法机构制止非法野生动物贸易并威慑不法分子。其他州属也应予以考虑。

执法

- 卫生部应提高有关含有动物衍生品的药用产品注册甄别程序。建议卫生部药品执法部门进行检查和突袭时提高警觉，例如寻找中文标识的产品，因为很多产品都是从中国进口的。
- 凡进口、收集、出售、购买、运输或者保存熊个体及衍生物的公司和个人，均视为违反《濒危野生动植物种国际贸易公约》和国家法律（《2010年野生生物保育法》、《1998年砂劳越野生生物保护条例》、《1997年沙巴州野生生物保护条例》、《2008年濒危物种国际贸易法》），必须予以起诉和惩罚，以示警诫。并表明政府对阻止濒危动物（例如马来熊）非法贸易的决心。宣称制品含有熊胆汁，无论实际成分是否如此，也将被视为违反《2010年野生生物保育法》。
- 野生生物保护部门、卫生部药品执法单位和市议会执法单位必须紧密合作，协调一致，并且经常性地检查中药店。基于国内和不同司法辖区里中医执业者的广大数目，这种方式能利用有限的执法资源，将那些未经注册且含有受保护野生生物成分的药品罚没，并将违法企业诉至法庭。这也将提高地方执法部门的工作水平。并向外界表明马来西亚政府在认定出售非法野生生物制品这一罪行上的严肃态度。
- 鉴于所调查的马来西亚东部两个州（沙巴州和砂劳越州）的中药店所售卖的胆囊皆来自于本土的马来熊，沙巴州野生生物部门和砂劳越林业公司必须共同采取执法行动打击马来西亚婆罗洲的马来熊偷捕和贸易活动，并阻止非法偷猎者提供的熊产品进入中药行业。
- 卫生部应检查在马来西亚的中药制造厂，确保含有野生生物成分的中药材的进口原料符合法律标准。建议卫生部在授予生产许可证之前采取更彻底的背景检查。
- 呼吁卫生部制定和实行一个正式的管控机制，以监管中药零售商的药品生产分配活动。而目前并没有相关的立法。

协调

- 负责野生生物（保护）及卫生防疫的有关政府部门之间应该更紧密地合作，以提高打击熊个体、衍生制品非法贸易的执法效率。与此相关的部门包括：野生生物与国家公园部、沙巴州野生生物部、砂劳越森林部、砂劳越林业公司、卫生部下属的传统和补充性医疗单位以及国家药品管制局、海关部门和地方政府等。
- 有关政府部门应与非政府组织、大学和其他研究中心组成战略结盟，开展有利于野生生物法律的监测、研究和教育工作，包括但不限于测试疑似含有熊胆汁成分的熊胆丸和其它产品。
- 政府、非政府组织和中医药机构应该通过诸如传统中医药国际会议这样的论坛，开展交流探讨有关合理解决中药中使用熊制品的课题。

采购

- 推广大型和持续性的公众教育活动。活动主题应突显中医药界非法熊胆贸易问题。并引导公众进行负责任和合法的中药产品采购。向公众介绍购买熊制品后需承担的保育和法律后果。
- 鼓励并推广中药企业和零售商使用草药代替熊制品。教导消费者应如何避免使用熊胆囊、胆汁及制品以及其中的原因。马来西亚华人医药总会也受促表明立场，反对在中药里使用熊个体及其制品。

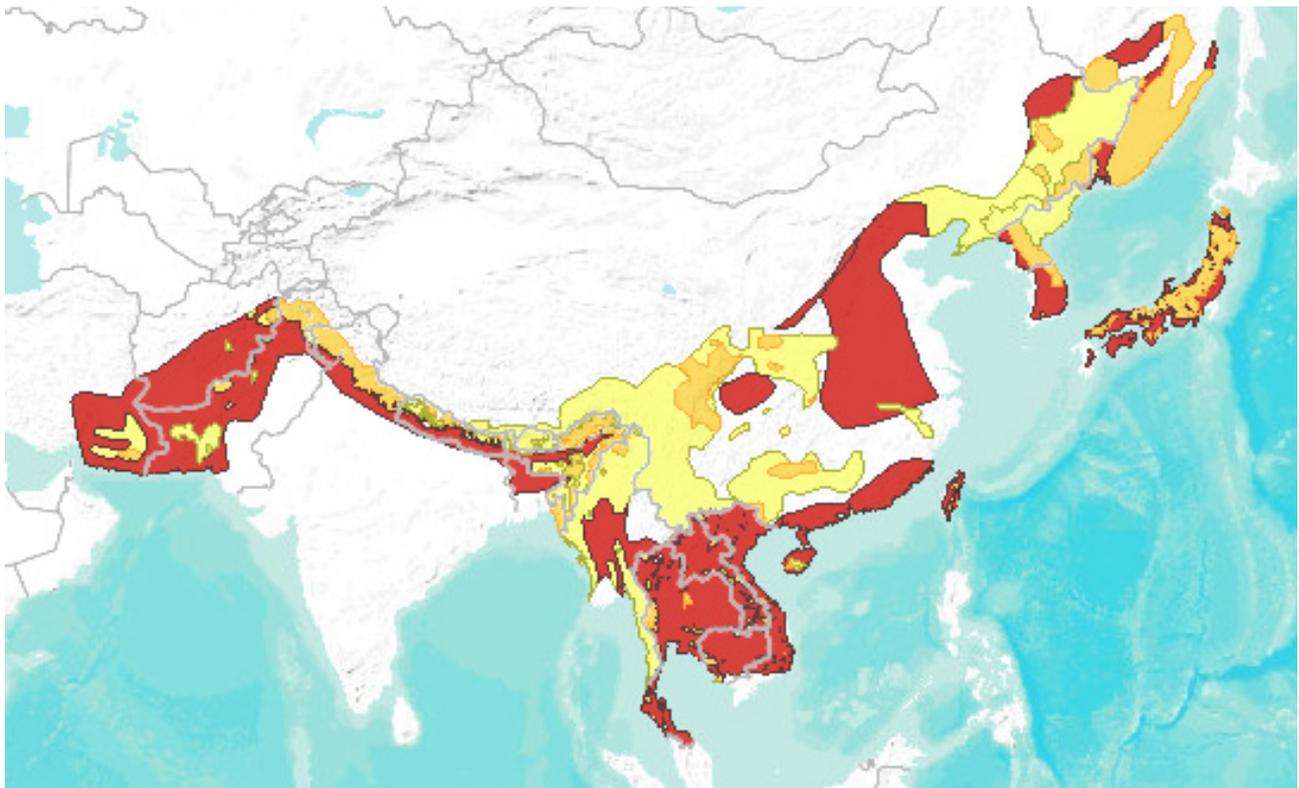
BACKGROUND

Status and distribution of bears in the wild

Of the eight world bear species, five are listed in Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), including the Asiatic Black Bear *Ursus thibetanus* and Sun Bear *Helarctos malayanus*, which are both at risk owing to their use in traditional Chinese medicine (TCM). An Appendix I listing means that all international commercial trade in these species, including their parts and products, is illegal. CITES Resolution Conf. 10.8 (Rev. CoP14) on the conservation of and trade in bears notes that “the continued illegal trade in parts and derivatives of bear species undermines the effectiveness of the Convention and that if action is not taken to eliminate such trade, poaching may cause declines of wild bears that could lead to the extirpation of certain populations or even species” (CITES, 1997).

The Asiatic Black Bear is the most commonly exploited bear species for use in traditional Chinese medicine (TCM) (Feng *et al.*, 2009; Foley *et al.*, 2011; Burgess *et al.*, 2014). It is patchily distributed across 18 countries in Asia (Figure 1) and is assessed as Vulnerable on the IUCN Red List (Garshelis and Steinmetz, 2008). The global population is thought to have decreased by between 30 and 49% over the past 30 years, with the decline projected to continue for at least the next 30 years (Garshelis, 2008). In addition to threat from trade, the Asiatic Black Bear is further threatened by habitat loss (Garshelis and Steinmetz, 2008).

Figure 1
Distribution of the Asiatic Black Bear, showing extant (amber) and possible extant (yellow) populations and historic distribution (red)

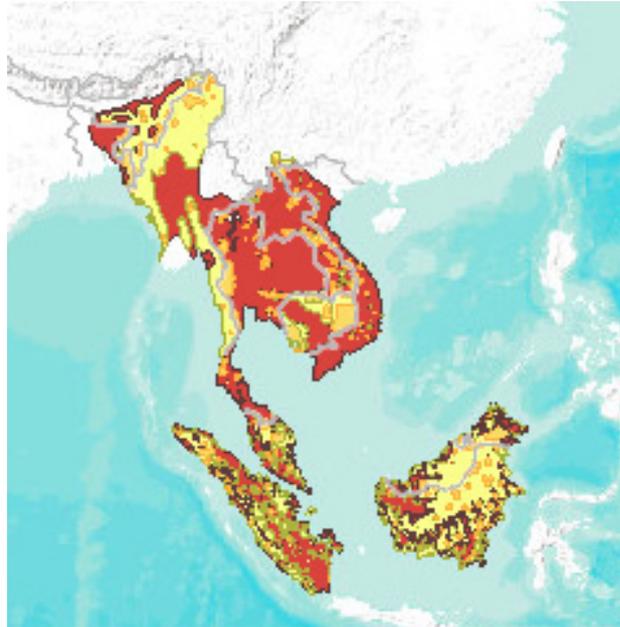


Source: Wildlife Conservation Society 2008. *Ursus thibetanus*. The IUCN Red List of Threatened Species. Version 2014.2. Reproduced with permission from IUCN Red List Unit.

Extant Sun Bear populations are distributed across South-East Asia, although the species has become extinct in Singapore and more recently in Bangladesh and China (Fredriksson *et al.*, 2008; Anwarul Islam *et al.*, 2010; Krishnasamy and Shepherd, 2014; Figure 2). The morphologically distinct population of Borneo is classified as a separate subspecies, *H. malayanus euryspilus* (Meijaard, 2004). The Sun Bear is assessed as Vulnerable on the IUCN Red Data List with a declining population reported across its range (Fredriksson *et al.*, 2008). With Malaysia's forests being increasingly fragmented as a result of logging, conversion for plantations and urban development, Malaysia's Sun Bears are particularly vulnerable to poaching for trade (Davies and Payne, 1982; Kawanishi and Sunquist, 2004; Wong, 2006). The Sun Bear is the only species of bear found in Malaysia and is known to be a target of poachers (Wong, 2006).

Figure 2

Distribution of the Sun Bear, showing extant (amber) and possibly extant (yellow) populations and historic distribution (red)



Source: Wildlife Conservation Society 2008. *Helarctos malayanus*. *The IUCN Red List of Threatened Species*. Version 2014.2. Reproduced with permission from IUCN Red List Unit.

Medicinal use of bear bile

Bile is a dark brownish-yellow, viscous liquid synthesized in the liver as a digestive juice and stored in the gall bladder. All vertebrates produce bile to aid in the adsorption of fatty acids and cholesterol, but bears (except the Giant Panda *Ailuropoda melanoleuca*) are the only animals that produce a significantly large amount of ursodeoxycholic acid (UDCA, also known as ‘ursodiol’) in their bile (Feng *et al.*, 2009). UDCA is an active pharmaceutical compound effective in treating a variety of ailments (Rubin *et al.*, 1994; Li, 2004; Amaral *et al.*, 2009), which makes bear bile a valuable ingredient in traditional medicines. *Fel ursi* is the pharmaceutical name for bear bile.

History of bear gall bladder and bile use

TCM is a form of therapeutic treatment originally developed in China (Wertz, 2011) founded on the belief that the consumption of animals and/or plants with curative properties will transfer these positive traits to the person consuming them (Donovan, 2004; Ellis, 2005; Drury, 2009). TCM and its concepts are a strong part of Chinese culture and lifestyle, passed down through the generations and reflected in the language, food, social interactions and spiritual beliefs.

The use of bear parts in TCM can be traced back around 3000 years when TCM first flourished. In the Ming Dynasty, a comprehensive medical volume *Beng Cao Gang Mu* (本草纲目) listed plant, animal, mineral and other items believed to have medicinal properties, including the Asiatic Black Bear (Watkins, 2002). Today, TCM continues to recognize the use of bear bile and gall bladder (Wiseman and Ellis, 1996). Scientific studies have found bear bile to be efficacious in treating severe eye problems, liver diseases and kidney malfunction (Jeng, 1992; Williams, 1993; Williamson and Phillips, 1999; Lee, 1999; Gao, 2002; Feng *et al.*, 2009).

Alternatives to bear bile use

The TCM community has identified as many as 54 herbal alternatives to bear bile (Pong *et al.*, 1999; Anon., 2005). Synthetic alternatives have been chemically developed in laboratories, and several pharmaceutical companies manufacture synthetic UDCA using bile from cows or pigs for use in conventional Western medicine to dissolve gallstones (Li *et al.*, 1995; Richards and Wang, 2006). However, many TCM practitioners reject these pharmaceutical substitutes because of their synthetic nature (Macartney, 2006).



Bear cub at a bear bile extraction facility in Ha Noi, Viet Nam

Bear bile extraction facilities

Bear bile extraction facilities, also commonly referred to as bear ‘farms’, were first established in China in the mid-1980s supposedly to reduce the pressure on wild bear populations. In reality, bear bile products from these facilities confuse users and enforcement authorities about the origin and legality of bear products, as it is difficult to differentiate between products from captive-bred and wild bears. Furthermore, the resulting sale of relatively cheap bile gives a false impression that wild bear populations are robust and not threatened (IUCN, 2012). The facilities may thus even fuel demand for wild-sourced bear bile and gall bladder, which encourages more poaching (Anon., 2007; Foley *et al.*, 2011). Another conservation implication is that bears are taken from the wild to stock these facilities (Phillips and Wilson, 2002; Feng *et al.*, 2009; Dutton *et al.*, 2011; Burgess *et al.*, 2014; Livingstone and Shepherd, 2014). In addition, inhumane treatment and abuse of bears are widely documented in these facilities (Maas, 2000; Li, 2004; Loeffler *et al.*, 2007; Calvari, 2008). Procedures to extract bile via catheters are often unhygienic, resulting in wound infection and contamination of extracted bile (Robinson *et al.*, 2006; Bekoff, 2011; Kikuchi, 2012).

More than 13 000 bears are thought to be held in bear bile extraction facilities across China, Lao PDR, Myanmar, Republic of Korea and Viet Nam (Kikuchi, 2012). China, where the sale of bear bile remains legal, reportedly holds more than 10 000 animals, mostly Asiatic Black Bears (Bekoff, 2011; Animals Asia, 2014). In the Republic of Korea, bile extraction from bears is illegal, but farmed bears can legally be slaughtered for their parts when they are 10 years old (Loeffler *et al.*, 2007). Commercial bear bile extraction is banned in Viet Nam, yet about 2400 bears remain in caged facilities (Nguyen and Nguyen, 2008; Llanos, 2012). In Lao PDR, the number of bears in farms was found to have tripled to over 120 animals from 2008 to 2012, and thought to be either taken from the wild in Lao PDR or imported illegally (Livingstone and Shepherd, 2014).

In September 2012, a resolution to phase out bear farming at the IUCN World Conservation Congress was passed. It recommended that all illegal bile extraction facilities should be closed down, the industry should not be expanded and no more bears from the wild should be used to stock captive facilities (IUCN, 2012).

The demand for TCM and bear products in Malaysia

Malaysia is both a key source and consumer of bear products. Trade in bear parts and derivatives for use in medicines and for consumption appears to be widespread and the products are often openly displayed for sale in Malaysia (Foley *et al.*, 2011). Three surveys conducted in 1991, 2001 and 2010 reported that more than half of the TCM shops surveyed in Malaysia were selling domestic and/or imported bear products (Mills and Servheen, 1991; Pereira *et al.*, 2002; Foley *et al.*, 2011; Table 1).

Table 1
Summary of the trade of bear products in Malaysia according to three previous surveys

Survey year and findings	1991	2001	2010
# of shops surveyed in Malaysia	13	73	137
% of surveyed shops selling bear products	100%; 70% selling gall bladders and 30% selling bile capsules	78%	55%; 77% in Peninsular Malaysia, 38% in Sabah and 27% in Sarawak
# of bear gall bladders observed (with price)	87 (USD 1–14 per g)	> 90 (price not determined)	160 (USD 0.33–13.09 per g)
Remarks	Asian demand for bears and bear parts placed pressure on international bear populations	China was considered the main supplier of bears and bear parts (i.e. 72% of trade)	China supplied bear parts to more than half of Asian countries investigated
Source	Mills and Servheen, 1991	Pereira <i>et al.</i> , 2002	Foley <i>et al.</i> , 2011

In May 2013, TRAFFIC and Ipsos Malaysia undertook a survey to understand public attitudes and awareness of bear bile in Malaysia. Awareness levels appeared to be low, with limited knowledge and many misconceptions about the conservation implications and illegal nature of the bear bile trade (Ipsos Malaysia, 2013).

TCM is recognized by the Malaysian government's Ministry of Health (MOH) as a component of the Traditional and Complementary Medicine Unit. In 2004, a national survey found that around 69.4% of the Malaysian population have used traditional and complementary medicine at least once in their life, with more than half using it on an annual basis (Anon., 2012). TCM practitioners in Malaysia, often referred to as *sensei*, include traditional medicine retailers, bonesetters, reflexologists, acupuncturists and physicians. Malaysia is also one of the top importers of TCM products from China (Table 2).

TCM in Malaysia continues to be influenced by developments in China. In 2010, the Malaysian and Chinese governments agreed jointly to develop a TCM research centre in Malaysia, with plans to promote Malaysia as a regional hub for TCM (Chow, 2010). The state of Sarawak also hosted the World Congress on Traditional Chinese Medicine in November 2012 (Tourism Malaysia, 2011).

Table 2

Top 10 markets for TCM exported from mainland China in 2010, the latest year for which statistics are available

Position	Country/Territory	Export (USD 10 000)
1	Japan	32 788
2	Hong Kong	27 381
3	United States	20 061
4	Republic of Korea	14 486
5	Malaysia	10 271
6	Viet Nam	9921
7	India	7747
8	Taiwan	7605
9	Singapore	6892
10	Germany	6762

Source: China Chamber of Health Products Commerce for Import and Export of Medicines.

LEGISLATIVE FRAMEWORK

In Malaysia, federal laws (usually called Acts) apply across the nation and take precedence over State laws enacted by State Legislative Assemblies (usually called Enactments or Ordinances). However, under the Constitution of Malaysia, some federal laws are applied differently in Sabah and Sarawak on a number of matters, such as national resource management and land.

Laws regulating the TCM industry in Malaysia

Table 3
Laws regulating TCM and the use of wildlife in Malaysia

Legislation	Regulations regarding TCM and the use of wildlife
Traditional and Complementary Medicine Act 2013	<ul style="list-style-type: none"> • Governs matters including the regulation of traditional and complementary medicine practitioners and services through compulsory registration and Practising certification by the Traditional and Complementary Medicine Council. This Council is the leading body governing the implementation, regulation and enforcement of this Act, with a wide scope and mandate, including the registration of practitioners, issuance of practising certificates and administer a complaints procedure. • Gazetted in February 2013; yet to come into force • Authorised officers have the power to enter a practitioner’s premises for inspection, verification or sample collection purposes. They may also issue an order requiring a practitioner to cease practice, and if this is contravened the offender is liable to a maximum fine of MYR 30 000 (USD 10 000) or two years’ imprisonment for the first offence.
Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984), incorporating latest amendments P.U.A 336/2006	<ul style="list-style-type: none"> • Compulsory registration of all pharmaceutical products in Malaysia with the Drug Control Authority (DCA), including TCM products containing bear derivatives • Compliance with the Good Manufacturing Practice (GMP) is mandatory for a manufacturing licence and product registration. Products must have adequate records and labels; applicants must trace all steps of production and distribution, and keep these records for one year past the expiry date. The Centre for Compliance and Licensing is responsible for the GMP inspections and its compliance. • An approved traditional medicine product is marked on the packaging by a registration number starting with the letters ‘MAL’ followed by eight digits and ending with the letter ‘T’ • Administered by the National Pharmaceutical Control Bureau, which serves as the secretariat to the DCA • The general penalty for offending individuals is a maximum fine of MYR 25 000 and/or imprisonment for up to three years for the first offence, and a maximum of MYR 50 000 and/or five years’ imprisonment for subsequent offences. Offending companies are liable to up to MYR 50 000 fine for the first offence, and MYR 100 000 for subsequent offences.
Medicines (Advertisement and Sale) Act 1956	<ul style="list-style-type: none"> • English or Bahasa Malaysia language labels listing all active constituents and ingredients, either its scientific names or other name descriptive of its true nature and the approximate percentage of each ingredient are mandatory for all medicines on sale • Offenders face fines of up to MYR 3000 (USD 1000) and/or imprisonment for up to a year for the first conviction. Subsequent offences can incur fines not exceeding MYR 5000 (USD 1667) and/or imprisonment for up to two years
Local Government Act 1976	<ul style="list-style-type: none"> • Local authorities can revoke or refuse renewal of business licences or permits, such as those of retailers violating wildlife laws, at the discretion of local councils (Part XIV Section 107) • Applicable only in Peninsular Malaysia

In addition to the laws above, the National Pharmaceutical Control Bureau has put in place the Drug Registration Guidance Document (DRGD) (Revision 2012). The DRGD is a reference guide for the registration process including quality control, inspection and licensing and post-registration activities of medicinal products. The DRGD is to be used in conjunction with national laws and regulations governing pharmaceutical use, including but not limited to, the *Sale of Drug Act 1951*, *Wildlife Conservation Act 2010* and the *International Trade in Endangered Species Act 2008*. It includes guidelines on the submission for the registration of medicinal products, submission of application for the licensing of manufacturers, importers and wholesalers.

In 2010, the state assembly of Selangor also passed an edict enabling local and district councils to revoke business licences for wildlife-related infractions. This novel initiative, called the Cancellation of Licences in Aid of Wildlife (CLAW) programme is led by the Selangor state government, Ministry of Natural Resources and Environment (MNRE), the Department of Wildlife and National Parks Peninsular Malaysia (DWNP) and the Malaysian Conservation Alliance for Tigers (MYCAT) – TRAFFIC is a member of MYCAT. Under this programme, the DWNP is required to report TCM dealers, restaurants and pet shops violating wildlife laws to the local councils. For second-time offenders, the state government may then revoke the business licences, upon verification of their violations. However, aspects of its implementation, including defining the different types of violation, are still under deliberation and no business operations have had their licenses revoked to date. Nonetheless, CLAW is a groundbreaking tool that enables both the federal and State governments to work together and take action against wildlife crime together and should be extended and adopted by other states.

Malaysia's wildlife laws and regulatory framework for CITES

Malaysia has been a Signatory to CITES since 1978 and its primary legislative tools are deemed sufficient to tackle the illegal wildlife trade in Malaysia (DLA Piper, 2014). Malaysia is classed as Category 1 (generally meeting CITES requirements) in the CITES National Legislation Project (CITES Resolution Conf. 8.4 (Rev.CoP15)), which assesses Parties on their readiness to take appropriate measures to enforce provisions of the Convention and to consider appropriate compliance measures. The following national and sub-national legislations pertain to wildlife conservation and protection and CITES enforcement:

International Trade of Endangered Species Act 2008

The Act regulates the import and export of CITES-listed species, including bears, and criminalizes the import, export, in transit and/or possession of scheduled species and/or its recognizable parts and derivatives without a permit. Any offenders are liable to a fine of up to MYR 100 000 (USD 33 333) for each animal, recognizable part or derivative of a scheduled species, but not exceeding MYR one million (USD 333 333), imprisonment of up to seven years or both. If the offence is committed by a corporate body such as a registered business, the fine is up to MYR 200 000 (USD 66 667) not exceeding MYR 2 million (USD 666 667), and the director, manager and officer of the corporate body may be jointly charged in court. The Act came into force in June 2010 across Malaysia.

Article 17 outlines the jurisdiction of Management Authorities, which includes the DWNP in Peninsular Malaysia, the Sabah Wildlife Department (SWD) in Sabah and the Sarawak Forest Corporation (SFC) in Sarawak. These authorities can cancel any permit, certificate or registration if there is non-compliance to any provision within the Act, if the permit was issued on the basis of false and/or misleading information, or if the holder of the permit has been convicted of an offence under the Act.

Customs Prohibition of Import and Export Order 2012

This came into force in March 2013, which aligns Malaysia's *International Trade of Endangered Species Act 2008* and the provisions within with the Customs Act, thereby facilitating better enforcement by Customs, including its border control officers.

Wildlife Conservation Act 2010 (Peninsular Malaysia and Labuan)

The *Wildlife Conservation Act 2010* is a federal legislation but does not apply to the states of Sabah and Sarawak, which have separate laws governing wildlife and environment conservation.

The Sun Bear is listed as a 'Totally Protected' species under the the *Wildlife Conservation Act 2010*, where the hunting, possession or trade involving Sun Bears is strictly prohibited. Those convicted of these violation, are liable to fine of up to MYR 100 000 (USD 33 333) and a jail term of no more than three years, or both. The penalties for hunting females and juveniles of 'Totally Protected' species are higher, including a fine of up to MYR 300 000 (USD 100 000) and/ or imprisonment of up to 10 years.

Significantly, the Act also provides penalties for products claiming to contain any parts of protected species or its derivatives. Those convicted of this crime can be fined up to MYR 20 000 (USD 6667) or to a prison term of up to one year, or both. In addition, anyone who imports, exports or re-exports any totally protected wildlife, its parts of derivatives without a special permit will be liable to a fine of MYR 30 000 – MYR 100 000 (USD 10 000 – 33 333) and to imprisonment up to three years, upon conviction.

A licensed dealer shall also maintain records, including the number of parts or derivatives of wildlife and the number of articles manufactured from any wildlife or part or derivative of any wildlife, which were purchased, acquired or sold, details of the source of acquisition and details of those whom articles were sold to. Any licensed dealer who contravenes this provision is liable to a fine of up to MYR10 000 (USD 3333) or a six-month jail term, or to both.

This Act defines enforcement officers as police officers, Customs officers or any public officers given mandate by the Director General of DWNP. DWNP also formed a special Wildlife Crime Unit that can perform duties across all states in Peninsular Malaysia and Labuan without boundary restrictions.

Sabah Wildlife Conservation Enactment 1997 (Sabah)

All trade of 'Totally Protected' species including Sun Bears is banned, with hunting and/or possession of such animals or their parts and derivatives incurring a fine of up to MYR 50 000 (USD 16 667) and/or jail terms up to five years. However, only animal species native to Sabah are listed. The trade of animal products requires a permit and the maintenance of a registry of the preservation, manufacture and sale of animal products by the permit holder. The Enactment is implemented by SWD.

Sarawak Wildlife Protection Ordinance 1998 (Sarawak)

Hunting or poaching of any animal in wildlife sanctuaries is prohibited and any offenders can be fined MYR 10 000 (USD 3333) and receive one year imprisonment. The Sarawak Forestry Department (SFD) and SFC are the main implementing agencies. Sun Bears are currently listed as 'Protected' which permits hunting provided an annual fee is paid to SFD. However, according to a senior officer of SFD, a hunting licence has never been issued for bears since the inception of the law in 1998 and the Department is unlikely to issue permits unless a particular animal has proven to be a nuisance to local residents (E. Lading, Sarawak Forestry Department, *in litt.* July 2012).

Commercial import and export of wildlife between Peninsular Malaysia and the two State jurisdictions of Sabah and Sarawak is restricted because of these different laws. As Sun Bears are 'Totally Protected' in Sabah and Peninsular Malaysia, the transport of bear and bear parts between the three administrative regions of Peninsular Malaysia, Sabah and Sarawak is prohibited unless a permit is acquired.

METHODS

Between 2010-2011, TRAFFIC conducted an extensive study on the scale and availability of bear parts across 13 countries and territories in Asia, and Malaysia had the fifth highest volume frequency of bear products on sale, behind Myanmar, Hong Kong SAR, Viet Nam and China (Foley *et al.*, 2011). Based on these findings, the present study was initiated to conduct a more in-depth investigation into the sale of bear gall bladders and bear bile products in TCM shops in Malaysia to further aid enforcement agencies in the country to take action against this trade, and to guide TRAFFIC's own work on reducing the trade in bears, their parts and their derivatives.

Surveys of TCM shops were conducted in all 11 States in Peninsular Malaysia and the Federal Territory of Kuala Lumpur, as well as the East Malaysian States of Sabah and Sarawak, between May and July 2012 (Figure 3). In each State, TCM shops in cities or townships with sizeable Chinese populations were visited, as these would be expected to reflect the main consumer market for bear products in TCM. From the 2010-2011 study (Foley *et al.*, 2011), 131 TCM shops were revisited to conduct a follow-up assessment.

TCM shop surveys were conducted by a TRAFFIC member of staff posing as a potential customer enquiring about bear gall bladder or bear bile products available for sale, using a semi-structured approach to gather data on the availability, quantities, authenticity, origin, price, and popularity of bear products and alternative medicines to bear bile, where possible. Judgements about whether retailers knew about the legal status of trade in bear products were made by soliciting their opinion on the possibility of taking the product out of the country and asking questions about the origins of products and cross-border transportation of bear gall bladder and bile products. Questions about the future supply of bear products often elicited suspicion among retailers, so conversations leading into the topic were used instead of direct questioning. Photographs of bear gall bladder or bear bile products were taken where possible. No products were purchased as part of the study.

Monetary values are reported in United States Dollars (USD), on a rate of USD 1 = MYR 3.

As the trade in bear products is largely concealed in Malaysia, data obtained in this study were limited by the retailers' willingness to reveal and discuss their stocks. For the purposes of the study, a retailer's word or confirmation was considered sufficient evidence to categorize a product as containing genuine bear derivatives, which they use to encourage sales because it is almost impossible to determine the biological origin and authenticity of bear gall bladder or bile products by sight alone in field situations (Coghlan *et al.*, 2012).

Figure 3
Map of key survey locations in Peninsular Malaysia including the capital city Kuala Lumpur (top), and East Malaysia (bottom)



RESULTS

Prevalence of bear gall bladders and bile products

A total of 365 TCM shops were surveyed across all States (and the Federal Territory of Kuala Lumpur) in Peninsular Malaysia (n = 293 shops), Sabah (n = 24) and Sarawak (n = 48) (Table 4). In 48% of the TCM shops surveyed across Malaysia, retailers openly claimed that their products contained authentic bear gall bladder and/or bile. Every State in Malaysia had bear gall bladder and/or bear bile products for sale. The rate was highest in Peninsular Malaysia, where 51% of the shops surveyed were found to sell bear products (n = 148), compared with 42% in Sabah and 35% in Sarawak. The States of Kelantan and Johor had the highest proportion of shops selling bear product (Table 4). Townships with the greatest proportion of shops selling bear product included Batu Pahat and Johor Bahru (Johor), Kota Bahru (Kelantan), Kuala Lumpur (Federal Territory), Kuantan (Pahang) and Ipoh (Perak).

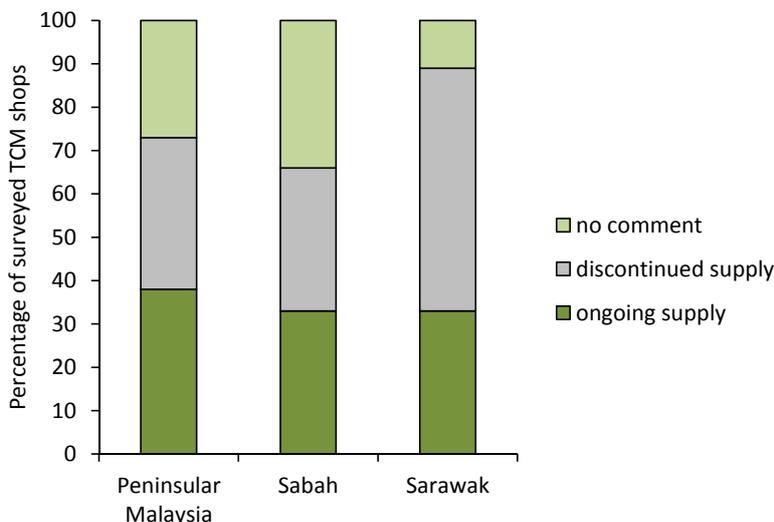
Table 4
Number of TCM shops surveyed across Malaysia confirmed by shopkeepers to be selling bear products and uncertain about the authenticity of their bear products

Location	# of shops surveyed	# of shops (%) confirmed selling bear products		# of shops (%) uncertain about authenticity of their products	
Perak	50	27	54%	16	32%
Johor	36	26	72%	7	19%
Kuala Lumpur (capital city)	34	21	62%	1	3%
Sarawak	48	17	35%	0	0%
Penang	37	16	43%	8	22%
Selangor	38	14	37%	4	11%
Pahang	25	13	52%	5	20%
Melaka	30	11	37%	3	10%
Sabah	24	10	42%	3	13%
Kelantan	12	9	75%	2	17%
Negeri Sembilan	11	4	36%	1	9%
Kedah	11	3	27%	3	27%
Terengganu	3	2	67%	0	0%
Perlis	6	2	33%	2	33%
Total	365	175	48%	55	15%

Fifty-five shops (15%) were uncertain about whether the *Xiongdan* (Chinese for bear bile) pills sold on their premises contained authentic bear bile. Interestingly, all retailers surveyed in Sarawak and Terengganu were definitive in their declarations about whether products did or did not contain bear derivatives, revealing no uncertainty about their products (Table 4); Terengganu however only had very small number shops and items for sale. The remaining 37% of TCM shops surveyed (n = 135) across Malaysia claimed not to sell products with bear ingredients. Nonetheless, the majority of these shops were selling yellowish *Xiongdan* pills which retailers declared were made from herbs only, purportedly retaining the name as they served the same function as bear bile.

Most of the surveyed TCM retailers that stocked bear bile products appeared to have ongoing supplies. Fewer than 20% of all TCM shops surveyed stated that the bear bile products in the store were the last stock available. Bear gall bladder supply seemed a little more limited. Of the 75 surveyed shops that sold bear gall bladders, 35% indicated that further quantities of bear gall bladders were available, whereas 40% of shops asserted that their current holding stocks were the last batch of bear gall bladder stock, although it was not clear why the stock was discontinued (Figure 4). For other shops, the available supply of bear gall bladder was uncertain because retailers were not willing to discuss reserve stock.

Figure 4
Indication of the continuity of bear gall bladder trade in Malaysia. There was no marked difference between the different States in Peninsular Malaysia.



Available stock was variable. Individual TCM shops may experience limited availability of bear parts as typically only one to two gall bladders are kept in each shop and a shop may be out of stock at a particular point of time. On numerous occasions, surveyed retailers did not have bear products at hand but attempted to contact their local suppliers or connections in the TCM business to fulfil customers' requests. Some retailers noted that they were awaiting the next supply from suppliers.

Forms of bear product

Bear products were found in various forms, including whole bear gall bladders, bear bile pills (i.e. *Xiongdan*), pure bile extract or powder, bear bile flakes in vials, dried gall bladder skin (one shop in Penang) and other manufactured products containing bear bile. Pills and gall bladders were the most common form found in TCM shops, evident in 65% and 43% of the shops surveyed, respectively (Figure 5). TCM shops in Sabah and Sarawak sold large quantities of raw bear gall bladders (24 and 94 gall bladders observed, respectively) (Figure 6) rather than *Xiongdan* pills, which were more common across Peninsular Malaysian States (present in 52% of shops surveyed). Prices ranged from MYR 0.40 (USD 0.13) for one *Xiongdan* pill to MYR 3360 (USD 1120) for a whole gall bladder weighing 38g. It should be noted that the prices include *Xiongdan* pills that may not necessarily contain bear bile. Overall, prices recorded in this survey were similar to those observed in the 2011 surveys (Foley *et al.*, 2011).

Figure 5
Number and percentage of surveyed Malaysian TCM shops in which different bear products were observed for sale. Note that some shops carried more than one form of product for sale

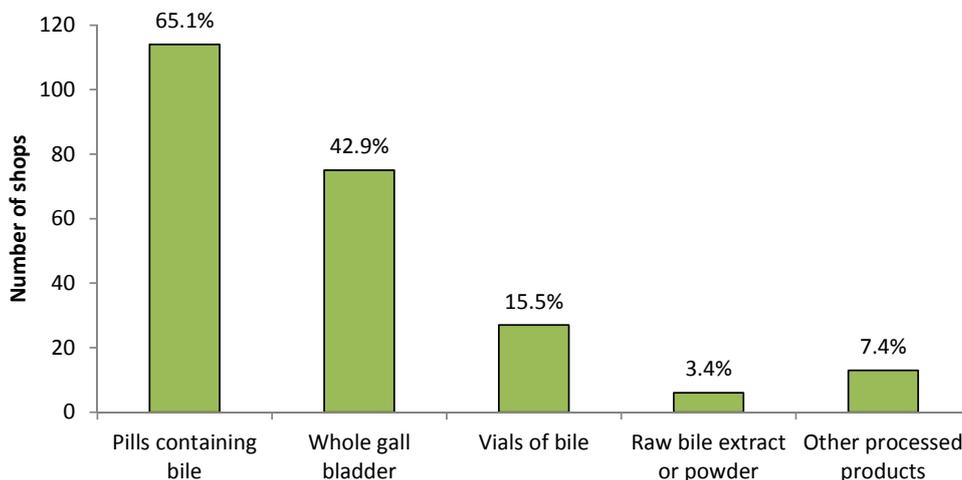


Table 5
Prices of various bear products for sale across Malaysia in USD

Location	Price range of gall bladders (per gramme)		Price for vials of bile flakes (per gramme)	Price for pills of bile (per pill)	Price for raw bile extract or powder (per gramme)	Other manufactured products (per item)
	Domestic	Imported				
Kuala Lumpur	2.05	2.60-9.40	3.20 - 16.00	0.32 - 1.60	11.51	
Perak	1.70-10.20	1.40-12.80	3.20	0.13 - 3.20	34.11	
Johor	7.70-19.70	1.70-25.60	1.60 - 6.40	0.32 - 3.20		
Kedah		4.30	3.84	1.60		
Kelantan	3.20 - 19.20		1.90 - 3.84	0.32 - 0.64		
Melaka	1.20 - 12.80	1.70 - 255.80	5.12 - 10.40	0.32 - 0.64		
Negeri Sembilan		8.50 - 21.30	3.20	0.64 - 1.60		
Pahang	1.00	3.20 - 9.60	16.00	0.27 - 1.60	1.06	1.02 (slide of powder)
Penang		2.10-33.40		0.32 - 32.00	85.30	
Perlis		25.60		1.60		
Sabah	5.50 - 42.60			0.16 - 0.32		8.00 (ointment)
Sarawak	3.70- 51.20	9.10		0.80 - 2.50		0.80- 2.50 (<i>Tieh Ta Wan</i> pills)
Selangor	7.60-35.80	1.70-34.10	1.90 - 8.00	0.32 - 1.60	21.32	
Terengganu		6.40		0.32	1.60	1.12 (medicinal plaster)

Pills

Xiongdan pills are clear gelatine capsules filled with bear bile extract or powder (Figure 6). Depending on the specific ingredients, the pills come in different shades of yellow, brown, white or black; the black ones supposedly contained pure bear bile extract. *Xiongdan* pills were sold in all States except Sarawak, and especially widely available in Johor, Perak and Penang, where they were recommended as the ‘common pill’ remedy for flu, fever and reducing ‘heatiness’, a TCM concept of imbalanced ‘yin’ and ‘yang’ energy. Some retailers alleged that *Xiongdan* pills were made entirely from herbs, whereas about 10% of retailers surveyed were uncertain about whether *Xiongdan* pills sold in their shop contained any bear bile. Typically, the pills were kept in containers without identifying labels or listed ingredients (Figure 6), so the authenticity of these products could only be judged by the word of the shopkeeper. Many retailers claimed that selling bear bile in the form of pills allowed them to evade detection of illegal sales and apprehension by authorities. Pills containing bear bile could be purchased individually, with prices ranging from MYR 0.40 (USD 0.13) up to MYR 96 (USD 32) per pill (Table 5). In numerous shops in Peninsular Malaysia, retailers demanded higher prices for pills allegedly comprising pure bear bile.

Figure 6. *Xiongdan* (bear bile) pills observed for sale in Malaysia. The yellowish ones (left) were the most common; these like many others were stored in unlabelled containers.



Photo credit: Lee Siow Ling / TRAFFIC

Most *Xiongdan* pills in this survey were reportedly manufactured locally. According to one sensei in Johor, there are three centres for the production of Chinese medicines, including *Xiongdan* pills, in Malaysia, situated in Kuala Lumpur, Penang and Johor. From there, the pills are then distributed to TCM shops through local distributors. This may explain why a large proportion of TCM retailers selling *Xiongdan* pills were only able to provide the name of the local supplier/distributor and unable to offer further information such as actual contents of the pill. Meanwhile, some stores claimed that the pills are made on-site by a *sensei* in the TCM shop by inserting scrapings of bear gall bladder into a gelatinous capsule. One such shopkeeper displayed a bottle of black-coloured pills with a bile duct of a bear gall bladder attached to it. Such pills were priced by the weight of bear gall bladder (i.e. per gramme) rather than the usual price-per-pill. *Xiongdan* pills manufactured in Peninsular Malaysia were also sold in the States of Sabah and Sarawak.

Whole gall bladders

Photo credit: Lee Siow Ling / TRAFFIC

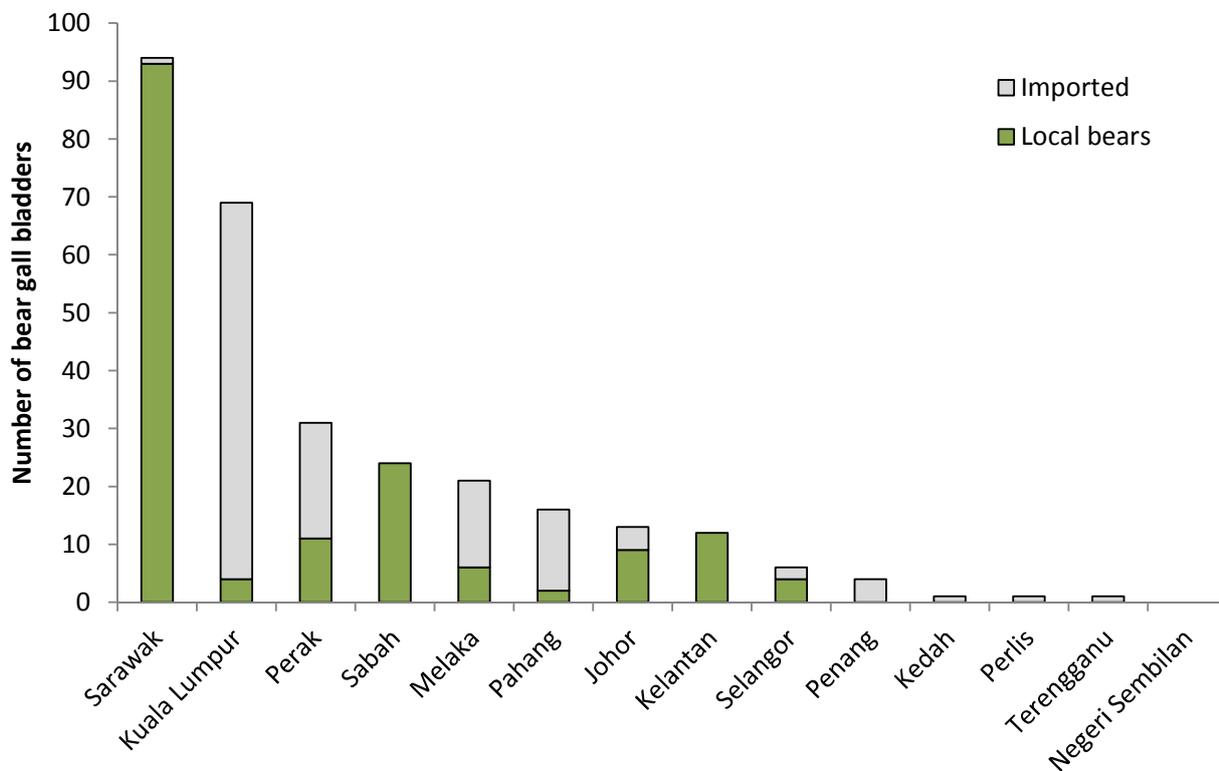


Bear gall bladders reportedly sourced from 'domestic' bears within Malaysia (left) and 'imported' bears in China (right).

A total of 293 bear gall bladders and five whole bear gall bladder skins were observed during the survey (Figure 7). Bear gall bladder was sold unprocessed, usually whole or in portions depending on the amount required. Individual gall bladders varied in size, colour, shape, texture and origin; these variables influenced the market value. Two visually distinct types of bear gall bladders were observed: small (3–15g dried or >30g fresh), elongated, black and sold as 'domestic bear gall bladder', or larger (30–100g or more, dried), with a flat or round centre, black or dark brown and sold as 'imported bear gall bladder'. The majority of bear gall bladders encountered during the survey were dried and old, supposedly the last remaining specimens from decades-old stockpiles. Only about 10% of surveyed shops had fresh bear gall bladders that were claimed to be recently acquired. These were predominantly found in Sabah and Sarawak, and to a lesser extent in Pahang.

Most (70%) gall bladders were priced between USD 10 and USD 80 for a whole gall bladder, with prices going up to USD 1120 (Table 5). Imported bear gall bladders were priced slightly higher (MYR 24 or USD 8 per gramme) than domestic bear gall bladders (MYR 23 or USD 7.67 per gramme) (Table 5). However, it is not known if the price difference is due to a perception that bear gall bladders from foreign sources are of superior quality. The lowest prices were recorded in Johor, Kuala Lumpur, Melaka, Selangor, Penang and Perak. Interestingly, in Melaka there were a few cases where the quoted price of gall bladders was extraordinarily high (Table 5). Instead of quoting a set price, some retailers wanted customers to make an offer for the gall bladder. Many retailers claimed that authentic bear gall bladders are very rare and therefore expensive, and also cautioned against purchasing cheap bear gall bladders as they are likely to be fake.

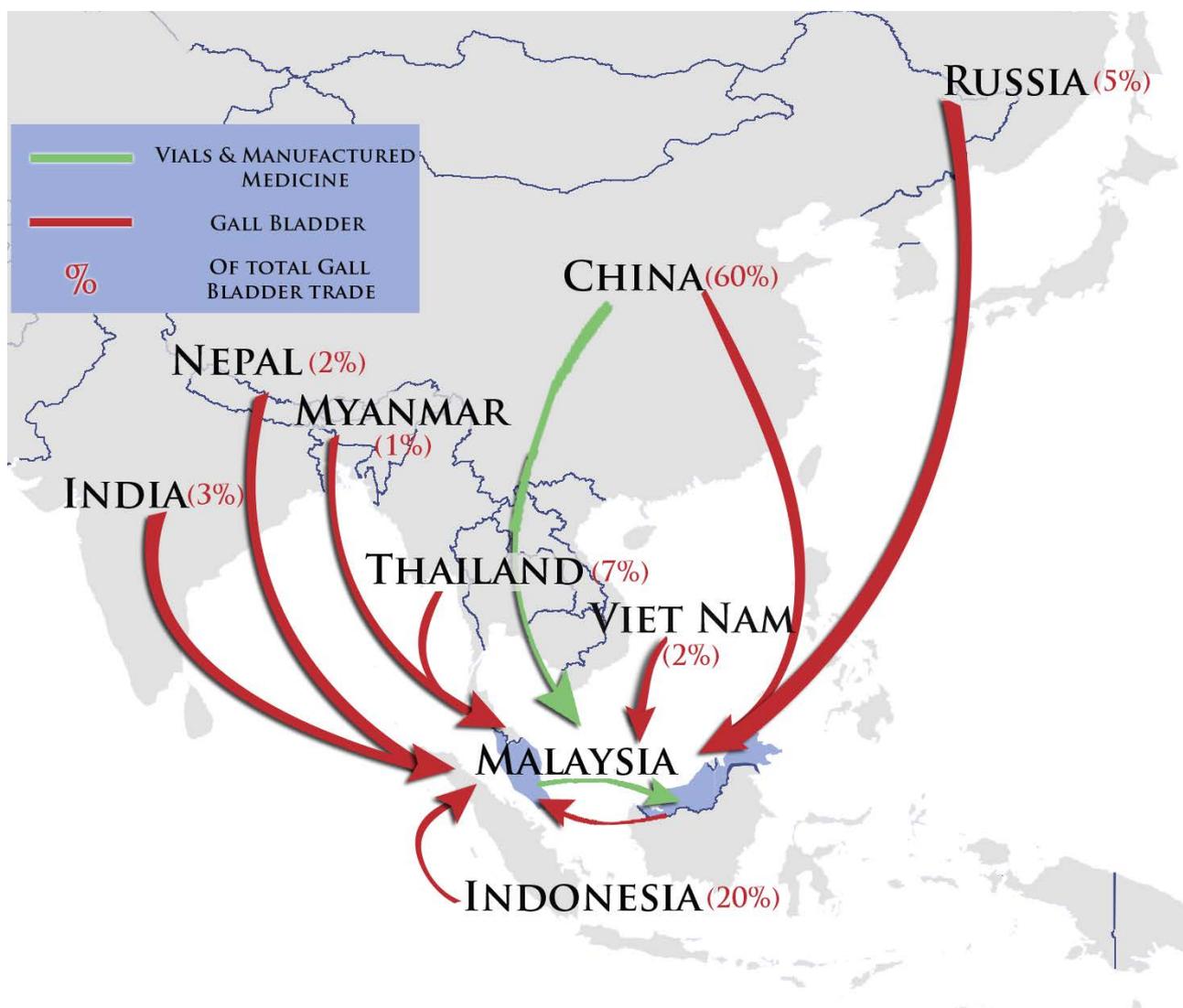
Figure 7
Number of bear gall bladders recorded in surveyed TCM shops across Malaysia



Approximately 20% of the TCM shops that were selling bear products offered bear gall bladders that were supposedly sourced from within Malaysia. Nearly 60% of all bear gall bladders observed for retail were claimed to be sourced from local bears (Figure 7). Retailers stated that the main sources were the native *Orang Asli* people of Peninsular Malaysia or indigenous people of Sabah and Sarawak who approached TCM shops to sell gall bladders from wild bears killed during their hunting trips. In particular, all TCM shops surveyed in Sabah and Sarawak that reportedly sold gall bladders sourced them from native Sun Bears. A local from Sibul, Sarawak, remarked that animal parts such as bear gall bladders could be bought from indigenous people working in the logging concessions in Sibul and other parts of Sarawak at lower prices than those offered in TCM shops.

In Peninsular Malaysia, domestically-sourced bear gall bladders reportedly originate from Sabah or Sarawak, as well as 'local forests', through either opportunistic or deliberate poaching. A few TCM retailers in Kelantan and Pahang stated that acquaintances holding hunting licences occasionally killed bears on their hunting trips when they "got lucky". For example, two weeks prior to the survey a shop in Kelantan claimed to have acquired a gall bladder from a local hunter who had been advertising by word of mouth. In Johor, a shopkeeper promised TRAFFIC staff an authentic bear gall bladder and four bear paws upon payment of MYR 3000 (USD 1000), for which he could mobilize people to hunt a bear immediately. A similar offer was made by a TCM *sensei* in Kuala Lumpur, who asked TRAFFIC staff to suggest a price for killing a bear in the wild. In addition, there were also accounts of dealers (non-TCM operators) from whom TCM retailers reportedly obtained their supply of animal parts.

Figure 8
Trade route map for bear gall bladders and other bear product imports entering TCM shops in Malaysia, based on retailers' claims of product origins



Map designed by Olivier Caillabet and Serene Chng

Of the TCM shops selling bear products, 24% offered imported bear gall bladders. China was quoted as the main source (60%) of imported bear gall bladders into Malaysia. Most retailers appeared to be aware of the country of origin of the bear gall bladders they had for retail; only 0.5% of shops surveyed were unable to cite the origin. Figure 8 shows the trade routes of imported bear gall bladders entering Malaysian TCM shops from other bear range countries, based on the information gathered from retailers. Two different kinds of bear gall bladders were said to be imported into Malaysia: the superior and more expensive gold-coloured bear gall bladders that were commonly reported to originate from China and to a lesser extent from Russia, and the black-coloured bear gall bladders that mostly originated in India and other countries in South-east Asia.

Vials, extract or powder

Bear bile flakes sold in vials were found only in TCM shops in Peninsular Malaysia. Vials were of 1g, 2g, 5g and 10g quantities and packaged into boxes of two or five (Figure 9). Both the individual vials and the container boxes were clearly marked with labels identifying the product and ingredients. An information leaflet was included in each box, describing the main uses of bear bile as well as recommended dosages in multiple languages including Chinese, English, Japanese and Korean. At least 104 vials, amounting to 726g of bear bile flakes, were observed during this survey. Although most shops claimed to stock only a small quantity of vials, some shops in Johor, Kuala Lumpur, Perak and Selangor reportedly had stockpiles, but these were not observed and the volumes in these stockpiles are not known.

The price of bear bile flakes sold in vials was relatively consistent across shops and states, ranging from MYR 4.80–48 (USD 1.60–16) per gramme (Table 5). The price was usually quoted per vial and negotiable when purchasing large quantities (i.e. a box containing 5 or more vials). Two shops quoted a high price as only one vial remained in their shops with no further incoming supplies.

Figure 9
Vials of bear bile flakes in 5g (left) and 1g (right) quantities were sold in packaged boxes. These products originated from Jilin, China

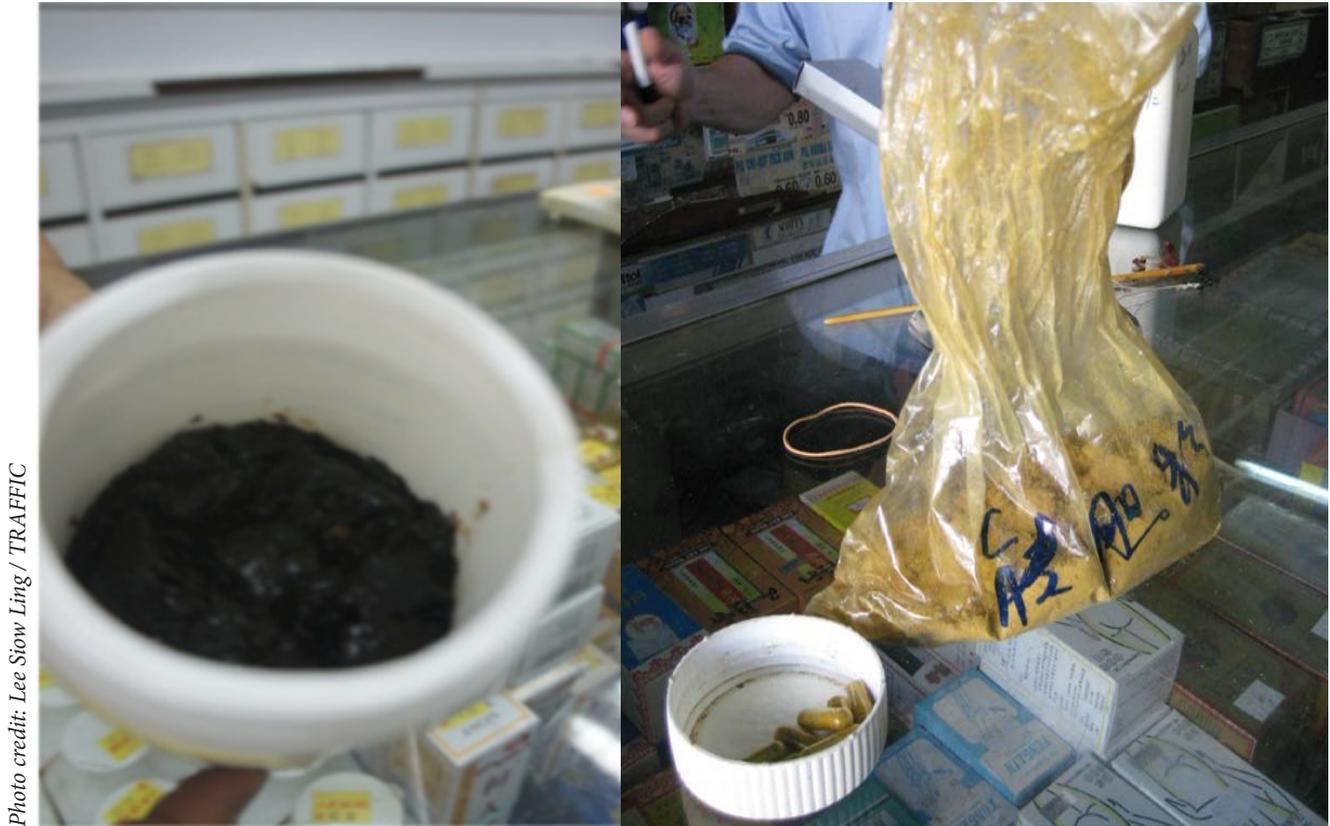


Photo credit: Lee Siow Ling / TRAFFIC

Unprocessed bear bile in the form of a viscous liquid (bile extract) or powder (Figure 10) comprised about 3% of bear products sold in TCM shops. This form of bear bile was sold by weight and was only observed in Peninsular Malaysia and not in Sabah or Sarawak. The TRAFFIC staff was told on numerous occasions that large stockpiled reserves of unprocessed bear bile were available for purchase, though there was no indication of whether these stocks were stored in-house or on other premises.

The value of raw bear bile extract was high, with prices averaging MYR 57 (USD 19) per gramme of extract. The price for powdered bile extract varied, ranging between MYR 3.18 and MYR 256 (USD 1.06-85) per gramme (Table 5) with the price presumably based on the purity of the powder and the quantity of bear bile contained.

Figure 10
Bear bile extract (left) and bear bile powder (right) observed for sale in Malaysia



China was the only reported supply country for bear bile vials, crude bear bile extract or powder and other manufactured medicines from bear derivatives found in Malaysian TCM shops. Bear bile sold in the form of extract or powder would either be extracted from a whole gall bladder from a killed bear or from bear bile extraction facilities located in China. Product labels on packaged bear bile items showed that bear farms in the city of Yanji in Jilin Province, China, were the main suppliers of vials (> 90%) sold in TCM shops in Malaysia. Another less common source was bear farms in Sichuan Province, China.

Of the 27 shops that had bear bile in the form of vials, extract or powder for sale in Malaysia, more than a third of retailers explicitly stated that stockpiles were abundant. A few retailers claimed to have ample stock to meet requests of any quantity from customers and some stated that stock could be ordered from China. Most retailers revealed that bear bile was brought into Malaysia from China concealed in personal luggage. One retailer added that he sometimes went on tours to China and Russia to acquire bear gall bladder and bear bile from these countries.

Other manufactured products

Various processed TCM products containing bear bile were recorded. These included *Tieh Ta Wan* (also known as a 'trauma pill', a round pill used for sports-related injuries), ointments, medicinal plasters and vials of powder used to treat mouth ulcers or sore throat. These products comprised 7% of all bear products found in TCM shops across Malaysia. Although these processed products were presented for retail in labelled packages, the only manufactured product type that listed bear bile (*Fel ursi*) as an ingredient were the tubes of powder. Retailers claimed that the other manufactured products contained bear bile despite its absence from the table of ingredients. Some retailers explained that the products were traditionally formulated with bear bile, but that bear bile had been removed from the ingredient list on the package since bears were protected animals. It is unclear if this means that products are no longer formulated with bear bile, or they still contain bear bile but are not mentioned in the ingredient list to conceal this. Slides of powder were sold cheaply at MYR 3.06 (USD 1.02) per slide containing 1g of bile. Generally, the exact quantity of bear bile contained in these powdered slides was unknown.



Photo credit: Serene Chng / TRAFFIC

Tieh Ta Wan (a manufactured pill) was reported to contain bear bile and was observed for sale in Sarawak. This product not previously recorded in the 2010–2011 survey. Note the MOH registration number on the packaging.

All recorded manufactured products containing bear bile originated from China. They were imported by local medicine traders and registered with the Malaysian government, as identified by the MOH registration number visible on most of these manufactured products. Addresses of Malaysian importers were also visible on most manufactured products.

Awareness of the illegality of sales

Overall, staff in 53% of the shops surveyed openly acknowledged that the sale of bear products in Malaysia is illegal (Figure 11), indicating that a significant level of illegal trade continued despite widespread awareness and recognition of laws. For example, a retailer in Penang showed a letter he received from DWNP notifying businesses of the new *Wildlife Conservation Act 2010* (Figure 12). He then explained the risks associated with selling bear gall bladders and other endangered animal parts as a result of the new law, stating these as grounds for the high price of bear products quoted. The letter, printed in Chinese and Malay languages, was sent out on 28 December 2010 notifying TCM retailers about clauses in the new wildlife laws relevant to the use of wildlife and parts and their implementation after a six month grace period. Some retailers justified the sale of bear bile in vials because “bears are not killed for this [purpose of extracting bear gall]”. Moreover, 30% of shops avoided or dismissed discussions of wildlife laws and the legal status of trade (Figure 11).

Figure 11
Responses from TCM retailers when asked about their awareness of the illegality of selling bear products in Malaysia, showing number of shops and percentage

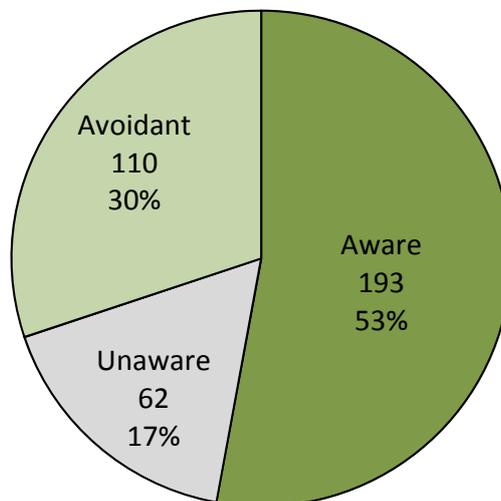


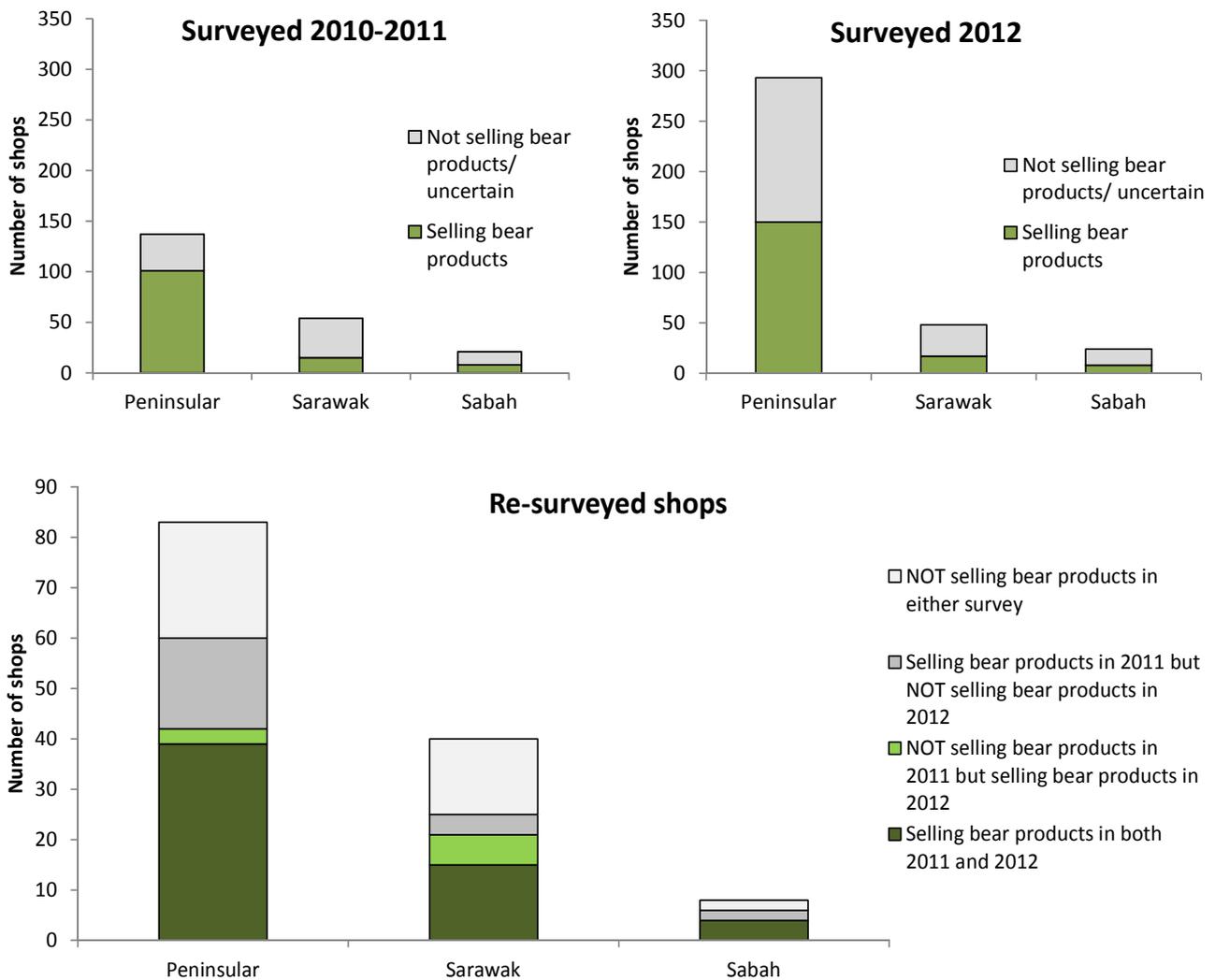
Figure 12
Notice issued by DWNP informing TCM shops of the Wildlife Conservation Act 2010 in Chinese language. Letters in Malay language were also issued to retailers.



Photo credit: Lee Siow Ling / TRAFFIC

Of the 365 shops surveyed in the current study, 131 shops were also visited in the 2010-2011 survey (Foley *et al.*, 2011). Of these, 58 shops (44%) continued to trade bear gall bladders and bear bile (Figure 13), with a breakdown of 47% of re-surveyed shops in Peninsular Malaysia, 38% in Sarawak and 50% in Sabah. Significantly, 24 shops revisited in the present survey appeared to have ceased selling bear products since the previous survey, suggesting a potential 18% decline in availability. However, it is unclear if this is due to enforcement efforts or other factors. In contrast, nine shops (7%) previously not found selling bear products (Foley *et al.*, 2011) were retailing bear products in the present survey, resulting in a net decrease of 11% in the proportion of TCM shops selling bear bile products in Malaysia between 2010–2011 and 2012 (Figure 13).

Figure 13
Sales of bear products in TCM shops in Malaysia according to surveys made between 2010 and 2011 (Foley *et al.*, 2011) and again in 2012 (current study). Comparison of findings in re-surveyed shops is also shown (bottom)



Alternatives to the use of bear



Photo credit: Lee Siow Ling / TRAFFIC

Alternative remedies to bear bile products for treating illnesses and ailments included porcupine bezoar (left) and cordyceps (right)

Overall, fewer than 30% of TCM shops surveyed were able and/or willing to suggest alternative remedies to bear products. In such cases, 80% of retailers recommended other animal parts or animal-derived products. *Pian Tze Huang*, a formula imported from China with ingredients of musk, ox gallstone, snake gall and *Panax notoginseng* (a species of pseudoginseng), was the most widely recommended alternative to treat liver diseases, cancer and inflammation (Table 6). Another popular suggested alternative to bear gall bladder was porcupine bezoar, an undigested mass of food in the gastrointestinal system of the animal (Box 1).

Plant-based products as alternative remedies to bear products were promoted by about 20% of these TCM shops (Table 6). In addition to examples listed above, other examples of established bear bile alternatives were Shi hu *Herba dendrobii*, Chuan xin lian *Herba androgaphitis*, Long dan cao *Radix gentiannae*, Xia ku cao *Spica prunellae* and Zhen zhu mu *Concha margaritifera usta*.

TCM retailers offering bear bile products were, perhaps unsurprisingly, less inclined to suggest alternative remedies, with a few sensei strongly reiterating that bear gall bladders and/or bile were the best product for treating liver diseases. Fewer surveyed shops in Sabah and Sarawak (< 20%) offered alternative options to bear bile.

Table 6
Proportion of TCM retailers offering alternatives to bear gall bladder remedies

Animal-based alternatives	% of shops	Plant-based alternatives	% of shops
<i>Pian Tze Huang</i>	52%	Cordyceps fungus <i>Ophiocordyceps sinensis</i>	30%
Porcupine bezoar	47%	Lingzhi fungus <i>Ganoderma lucidum</i>	14%
Cow bezoar	4%	Ginseng <i>Panax quinquefolius</i>	10%
Saiga horn	1%	Herbal mix prescribed by <i>sensei</i>	20%
Bird nest	1%	Supplements for liver (e.g. nutans tea, HerpaR, Thomson liver supplements)	29%

Box 1: Porcupine bezoar in TCM – an emerging conservation threat?

According to retailers, porcupine bezoar is believed to treat diabetes, dengue fever, typhoid, epilepsy and hepatitis among many other conditions, and prices have increased exponentially in the past few years following recent claims of its cancer-curing properties. Many retailers said that the efficacy of porcupine bezoar even supercedes bear gall, and that the product is popular among wealthy locals for optimizing general health. Interestingly, a few retailers noted that “this [bezoar] is also illegal”. Some retailers revealed photographs of slaughtered porcupines to attest to the authenticity of the bezoar.

Three species of porcupine are native to Malaysia. The Brush-tailed Porcupine (*Atherurus macrourus*) and Malayan Porcupine (*Hystrix brachyura*) are in the ‘Hunted Wildlife Species’ list of the *Wildlife Conservation Act 2010*, and can be hunted and traded with a licence. Both species are also in the Sixth Schedule, which means *Orang Asli* can hunt them only for subsistence without permits (no commercial trade allowed). The Long-tailed Porcupine (*Trichys fasciculata*), like the Sun Bear, is on the *Wildlife Conservation Act 2010*’s ‘Totally Protected’ list.

Elsewhere in South-East Asia, porcupines are also being poached and smuggled to fuel the TCM demand (Bell, 2014). A cursory internet search revealed many websites claiming to sell porcupine bezoar, suggesting that demand is escalating. Declines in the trade, availability or demand of bear products in TCM could result in increasing demand for porcupine bezoar as an alternative by consumers. Close monitoring of the trade in porcupine bezoar is strongly recommended and pre-emptive efforts should be taken to deal with this emerging issue.



Photo credit: Lee Siow Ling / TRAFFIC

Porcupine bezoar for sale in TCM shop

DISCUSSION AND OBSERVATIONS

As with the trade in other wildlife species, both the demand and supply of bear gall bladders and bear bile in Malaysia are driven by economic and social factors. An increase in wealth of local populations (and hence an increase in potential consumers) coupled with traditional beliefs in the healing properties of bear bile result in high profits from the retail of bear products. Add to this the low risk of prosecutions and subsequent penalties, and Malaysians regardless of financial status continue to participate in bear poaching and trade (Shepherd and Shepherd, 2010; Burgess *et al.*, 2014).

Actors along the trade chain

Figure 14
Diagram of the trade chain indicating the flow of bear gall bladders and bear bile from source to consumer

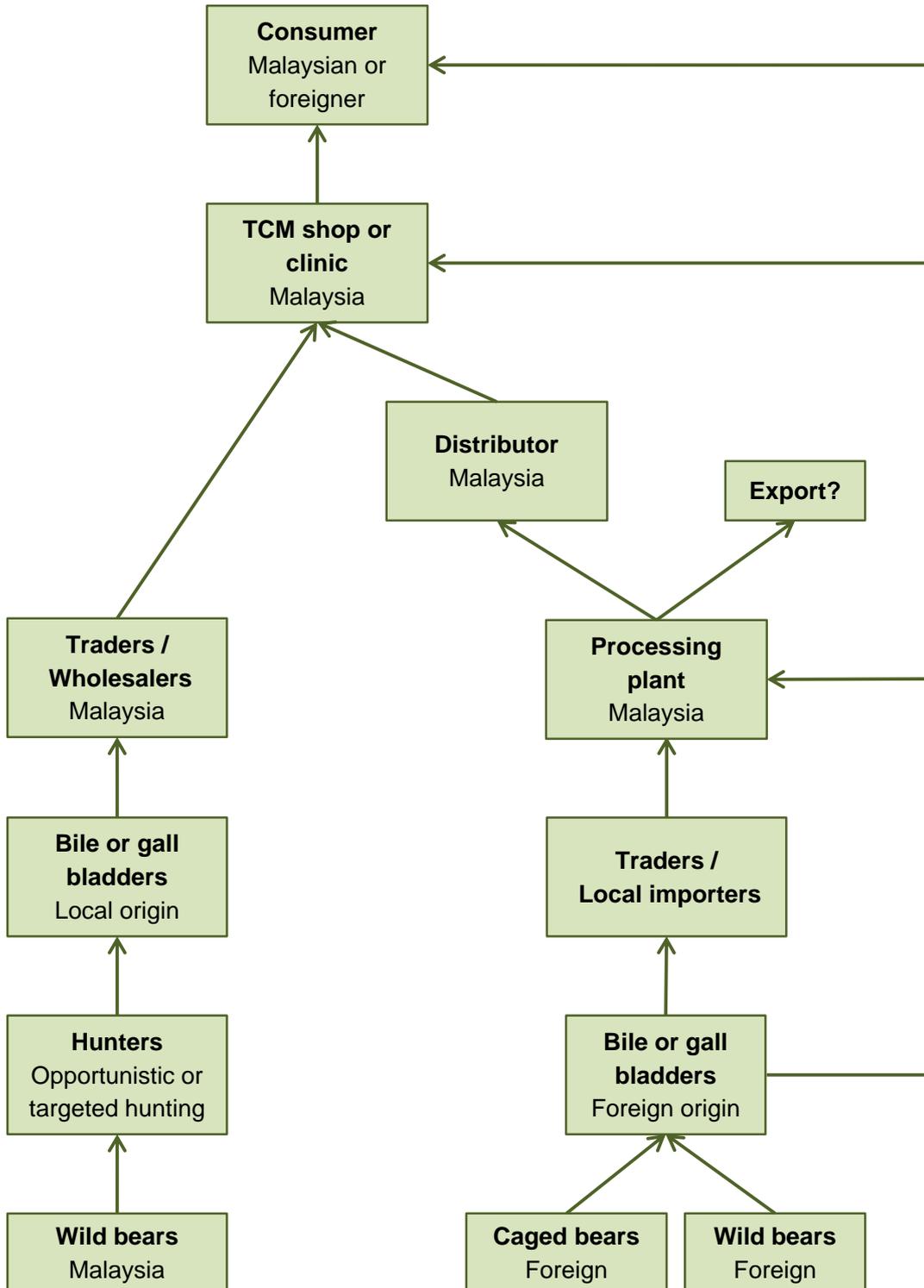


Figure 14 illustrates the trade chain for bear gall bladders and bear bile products in Malaysia. Most indigenous people are opportunistic hunters of bears in Malaysia, except in Sarawak where certain tribes regularly target bears for food (Jessup and Vayda, 1988; McCracken, 2011). Bear gall bladders are then sold to middlemen or directly to retailers for sale as traditional medicine. During this survey, TCM retailers revealed that indigenous people are their main source of many native animal parts such as monkey bezoar, porcupine bezoar, deer tails and bird nest.

Foreign bear products available in Malaysia included bear gall bladders and bear bile, either illegally imported by local enterprises or smuggled into the country in personal luggage. Both routes are in direct violation of CITES; there are no CITES-registered captive breeding facilities for bears from which legal products can be imported. China has previously been found to be the main source of most bear bile products (Hsieh, 2000; Ho and Govind, 2001; Chen *et al.*, 2002; Pereira *et al.*, 2002; Togawa and Sakamoto, 2002; WSPA, 2007; Foley *et al.*, 2011), a finding that was confirmed in this study. This highlights the need for better monitoring and enforcement at points of entry and exit of implicated countries (Burgess *et al.*, 2014).

Within Malaysia, Malaysian-owned as well as foreign-owned (Hong Kong) companies in Johor, Kuala Lumpur, Penang and Selangor were found to be manufacturing medicine containing bear bile, suggesting that bear bile must have been imported for the production process. Although this violates CITES and Malaysia's *International Trade of Endangered Species Act 2008*, these businesses were granted licences to operate within Malaysia by the Malaysian Investment Development Authority. In addition, locally based enterprises in Johor, Kuala Lumpur and Penang, the main distributors of *Xiongdan* pills found in almost all TCM shops in Peninsular Malaysia, were reportedly thriving. It is likely that these growing operations will play a larger role exporting bear products to other consuming markets beyond Malaysia.

In many cases, TCM shop owners are trained or self-taught *senseis* who offer consultations within their shops. From interviews and observations during this study, the majority of customers visiting TCM shops appeared to be middle-aged or retirees of Chinese descent, and to be the family members who oversee the household needs. Often, the relationship between TCM practitioners and their customers is defined by mutual trust and rapport. Whenever requests for bear gall bladders or other illicit animal parts were made, TCM retailers, especially in smaller towns and communities, appeared to feel a responsibility to supply the product. Notably, the same retailer will turn down a request for bear products by an unknown visitor. In contrast, TCM retailers in larger urban centres with potentially more customers were relatively indiscriminate with their customers.

Conversations with retailers revealed that the cheap and widely-available *Xiongdan* pills were as popular as paracetamol pills in relieving the symptoms of flu and fever. Pure bear bile in vials was less common but still easy to obtain inexpensively, although many retailers commented that sales of bear bile had declined over the years.

The sale of bear gall bladders was more discreet, with the shop owner often consulted before gall bladders were displayed to customers. Many retailers also stored gall bladders in locations away from the shop or hidden in different rooms within the shop premises. A few retailers revealed that they had stocked up on bear gall bladders for particular customers who regularly purchase them. Many retailers reported that the demand for bear gall bladder had declined dramatically, with many consumers switching to alternatives perhaps because of the high price, and with well-educated younger generations increasingly favouring conventional medicines. Nonetheless, the consumer demand for bear gall bladders persists.

Some retailers downplayed the impact and severity of bear bile trade, on the premise that bears were not always killed in the process of bile collection. Some even conceded that the use of these products for health purposes took precedence over the survival of bears. In Sabah, some retailers encouraged purchasing multiple bear gall bladders because one was considered too small to be effective.

On a positive note, although this was not quantified in the study, it should be noted that many *senseis* appeared aware of their professional responsibility and do not agree with the use of bear bile. A promising start to engaging the TCM community was made when TRAFFIC was invited by the Federation of Chinese Physicians and Medicine Dealers

Association of Malaysia to speak at the 12th World Congress on Traditional Chinese Medicine held in Kuching, Sarawak in 2012. A follow-up meeting in March 2015 will see TRAFFIC and the Federation plan a series of activities to reach out to traders and physicians on this issue.

Legal and regulatory framework issues

Hunting and poaching

Sun Bear hunting in Malaysia is still a prevalent threat, as seen from the 38 seizures of bears or bear parts involving at least 98 individuals in Malaysia (Burgess *et al.*, 2014) and the snaring of Sun Bears in Belum–Temengor Forest Complex (Krishnasamy and Or, 2014). The survey results show that Malaysian Sun Bear gall bladders are entering the TCM trade and therefore actions need to be taken to protect them.

Sarawak's *Wildlife Protection Ordinance 1998* and Sabah's *Wildlife Regulations 1998* are outdated and revision of the laws would ensure that these two laws are on par with the *Wildlife Conservation Act 2010* and *International Endangered Species Act 2008* – TRAFFIC are involved in discussions with the relevant agencies to initiate the process. Furthermore, the Sun Bear is not listed on Sarawak's *Wildlife Protection Ordinance 1998* 'Totally Protected' list. As clauses are subject to a permit requirement, both legislations are weakened by a lack of effective regulation of permits (DLA Piper, 2014). Under Sabah and Sarawak laws, native tribes inside national parks have the right to gather forest resources for subsistence use only and not for sale. However, this regulation is difficult to enforce and officials often overlook such illegal activities (Harowitz, 1998). Insufficient funding, a shortage of enforcement capacity and a lack of incentive are widely acknowledged by enforcement authorities as the main reasons for inadequate patrolling of protected forests throughout Malaysia (Bennett *et al.*, 1995; Tuuga, 2009; Ng and Lee, 2010; Wong, 2012; Krishnasamy and Or, 2014).

Selling and trading

All TCM businesses registered with local councils in Peninsular Malaysia have been issued a notice about the new *Wildlife Conservation Act 2010* by DWNP. Most of the TCM shops surveyed appeared to be aware that the sale of bear product was illegal, and the trade ban was cited as a main reason for not selling bear products. For others, however, the ban merely meant that sales had to be covert.

TCM shops found to be selling bear bile in the 2010–2011 survey (Foley *et al.*, 2011) had been reported to the authorities (DWNP in Peninsular Malaysia, SWD in Sabah and SFC in Sarawak) upon the completion of the survey and were monitored for progress. In some cases, successful raids have occurred. After the 2012 survey, all information was also submitted to DWNP headquarters, its respective State offices and those in Sabah and Sarawak. Some cases resulted in follow-up actions, seizures and subsequent prosecution against the sale of illegal wildlife parts by DWNP. TRAFFIC was also informed by the enforcement department of the NPCB that action was also taken against retailers of unregistered medicinal products. Bear bile products, such as pills, have been confiscated for forensics testing. Information on enforcement action from law enforcement agencies is not always available to TRAFFIC or the public, especially if it involves ongoing investigations, but TRAFFIC continues to co-ordinate with them on checking of shops selling illegal wildlife products including bear parts and products. When retailers were questioned during the current study about enforcement, a few reflected that raids from authorities had been conducted on their premises but these clearly did not deter many retailers from continuing the illegal trade in bear products post-raid.

From 2000 to 2011, 44 gall bladders and two bile products were seized in Malaysia (Burgess *et al.*, 2014). Of these, only one case of a gall bladder seizure resulted in a fine of USD 316 (Burgess *et al.*, 2014). The sheer number of TCM shops makes consistent checks by MNRE challenging. Furthermore, due to the variability of TCM products and treatments, the difficulty of confirming the presence of bear in processed products, and the varied availability of bear products in individual TCM shops, it is challenging for law enforcers to carry out on-the-spot enforcement of TCM businesses reported to be flouting the law. Support from local councils would increase the capacity of law enforcement.

Shop owners and practitioners selling bear parts were observed to be adept at circumventing the law. For example, some retailers only kept small amounts of bear products in the shop to minimize fines if prosecuted, or removed references to bear bile from labels. Retailers eager to make sales also imparted inaccurate information, encouraging TRAFFIC staff to purchase bear gall bladders from Malaysia for use overseas or claiming that they could be legally bought overseas. Many retailers offered to package bear gall bladders to evade detection at airports or advised that x-ray scanners will not detect bear gall bladders in personal luggage. Some added that detected bear gall bladders would only be confiscated, with no further repercussions such as fines or jail term. This perpetuates the idea that carrying bear parts and products in and out of Malaysia is legal, accepted or easily carried out. More rigorous enforcement is needed to act as a deterrent when faced with such limited understanding of legislation, biased interpretation of wildlife laws and complacency.

Allegations of corruption by enforcement officers charged with issuing fines for illegal practice were also recorded. One retailer recounted how “[enforcement officers] come when they need money, we keep our [bear bile in vials] away so that we don’t have to pay them”. Another, when asked about taking bear product out of Malaysia, replied “...it may be easy to take it out of [Malaysia] but not easy to take it into another country. Here, we can pay them but they don’t take your money [in a particular East Asian country]”.

A number of shops also had other illegal or protected wildlife products for sale, such as porcupine bezoar (Box 1), rhino horn and saiga horn. In light of this, more frequent checks on TCM shops is required as the sale of endangered and illegal wildlife products for TCM extends beyond bear bile.

Labelling and traceability

Photo credit: Lee Siow Ling / TRAFFIC



Left: Ingredient list of the manufactured product *Tieh Ta Wan*, which fails to list bear on the label, despite being reported to contain bear bile by retailers.
 Right: Fake bear gall bladder observed by one of the authors

Claiming that manufactured products contain bear bile, regardless of the actual contents, is an offence under the Wildlife Conservation Act 2010. Despite this, mislabelling or lack of labelling is a tactic used to circumvent the law.

Products that retailers verbally claimed to contain bear bile were labelled with the names and addresses of local importers and manufacturers, but only a tiny proportion of products had *Fel ursi* listed as an ingredient in the product. Many of the *Xiongdan* pills observed during this survey were packaged without labels or labelled with handwritten Chinese characters. A dozen other product types had the Chinese character for bear bile (熊胆, sometimes transcribed into *pinyin* pronunciation as *Xiong dan*, *Shyong dan* or *Siong dan*) in the name of the product but not in the ingredient list. These contravene the *Medicines (Advertisement and Sale) Act 1956*'s requirement that medicinal substances be labelled in English or Malay.

Fake bear products marketed as bear products continue to increase the demand for bear products, regardless of their authenticity, and hamper enforcement efforts (Mills and Servheen, 1991). Gall bladders of domestic animals such as pigs

and cows have been passed off for sale as more expensive bear gall bladders in Malaysia (Mills and Servheen, 1991; Pereira *et al.*, 2002) and other countries (Lau *et al.*, 1994; McCracken, 1995; Chestin, 1998; Chang *et al.*, 2012). These cannot be reliably differentiated by sight.

Reliable identification of genuine bear derivatives requires costly and largely inaccessible laboratory analysis (Peppin *et al.*, 2008). Forensic facilities and techniques to test for the presence of bear in TCM are available in Malaysia, but the sheer volume of products that may contain bear bile makes testing on such a large scale unviable.

Role of the Ministry of Health

MOH should put in place a more thorough screening process to weed out TCM products containing bear bile, especially those not labelled according to the *Medicines (Advertisement and Sale) Act 1956*. They have a critical role to play in ensuring that such products never make it to markets. TRAFFIC has initiated dialogue with the relevant departments within MOH to explore ways forward.

As TCM businesses operate under the auspices of the MOH, this Ministry has a critical role in ending the trade of bear bile products through its keen oversight on processes, protocols, regulation and enforcement. The DRGD states that it is to be used in conjunction with the *Wildlife Conservation Act 2010* and *International Trade in Endangered Species Act 2008*, meaning that drugs containing illegal wildlife products such as bear parts are not legally allowed for sale. In this survey, at least one medicinal product containing bear bile in the ingredients list had MOH registration numbers as well as GMP certification. These have been shared with NPCB and investigations are currently ongoing to deregister these products.

The process through which drugs containing wildlife products are registered involves both NPCB and DWNP. The initial screening process by NPCB identifies medicinal products which contain protected wildlife and, if they are listed on any of the wildlife laws, requires confirmation from DWNP that the applicant has the necessary permits. After screening, the product is checked to ensure compliance with safety standards through testing for potentially harmful substances. Animal derivatives are not tested for or identified. NPCB notifies DWNP when a medicinal product containing wildlife has been successfully registered.

Enforcement staff in MOH clarified that only processed products in pharmaceutical dosage forms (e.g. bear bile pills) are considered to be medicine and can be enforced under the *Control of Drugs and Cosmetics Regulation 1984*; any wildlife products in their raw form (e.g. gall bladder) found in TCM shops can only be confiscated by wildlife department officials. This gap in enforcement could be rectified by MOH and wildlife department officials carrying out joint raids of TCM premises.

The new *Traditional and Complementary Medicine Act 2013* is potentially a powerful tool to fight illegal bear bile trade; however it only covers traditional and complementary medicine practitioners, not retailers of TCM products. TCM products are currently considered to be over the counter products and do not require a license from the pharmacy department. As such, retailers of TCM products are currently self-regulated. The Traditional and Complementary Medicines Division of MOH is working closely with relevant stakeholders, including governmental agencies such as NPCB to develop a proper mechanism to regulate the dispensing activities of TCM medicine retailers (Teh, Y. L. *in litt.*, April 2015). The *Traditional and Complementary Medicine Act 2013* also does not have specific provision to govern the prescribing activities of protected animal parts or derivatives by practitioners.

Malaysian-based manufacturers of pharmaceutical products, including those allegedly containing bear bile and derivatives, are regulated by NPCB and subjected to GMP inspections. Once a registration number has been assigned to a particular product following a satisfactory GMP compliance audit of the said manufacturer and satisfactory evaluation of the registration dossier, the manufacturer has to apply for a Manufacturing License which allows the manufacturer to manufacture registered products listed in the license. The Manufacturing License is to be renewed annually and the manufacturer subjected to routine GMP inspection scheduled by NPCB.

Co-ordination between government agencies

Insufficient co-ordination between relevant government departments in Malaysia creates confusion about the legitimacy of bear trade. The MOH may unwittingly approve a TCM product containing bear derivatives for sale within Malaysia, while MNRE has regulations strictly prohibiting the sale of the very same product. This complicates enforcement efforts and sends an ambiguous message to the public regarding the Malaysian government's stance on bear trade.

Many TCM retailers that have faced enforcement action for selling unregistered drugs are repeat offenders, and MOH's enforcement officers currently does not have the power to revoke business licenses. At the local authority or council level, respective law enforcement units can take action against illegal activities taking place within business premises in their jurisdiction. Drawing the attention of local councillors and their law enforcement personnel to the issue of illegal products being sold in TCM shops would elevate the seriousness of the issue, and serve to strengthen the message that selling wildlife products illegally is a serious matter that is being considered by all arms of the Malaysian government. It also serves to improve inspection and enforcement efforts at a local level. In Selangor, business permits of retailers found to be flouting the laws can be suspended under the CLAW programme, creating a strong deterrent effect. This programme should be considered and adopted by other states too, and expanded to include wildlife related offences under the *Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984)*.

As the DWNP have already issued notices to all TCM shops in Peninsular Malaysia, SWD and SFC may wish to do the same in Sabah and Sarawak to ensure that retailers there are also aware that selling bear parts and derivatives is illegal. Harmonising and socialising the laws between agencies could aid this co-ordination.

Support from and engagement with the TCM community is essential to reduce the trade in bear products, through reducing demand by promoting herbal alternatives and regulating the sale of endangered species and illegal products. The Federation of Chinese Physicians and Medicine Dealers Association of Malaysia issues certificates to qualified practitioners of TCM and requests that all registered members comply with medical ethics and business ethics to protect the reputation of the Chinese medicine sector. The engagement by the conservation community with the Federation to align messages against the unsustainable and illegal use of wildlife products in TCM is crucial to an industry-led reduction in the use of bear parts and products.

This study did not include more discreet TCM operations that provide consultation outside office hours; surveys of these could uncover additional trends and insights, especially if stronger enforcement efforts eliminate the open trade of bear products in TCM. Differentiating between retailers, sub-wholesalers and wholesalers of bear products could also reveal further insights into available stockpiles and their value. Further investigation is also needed of local factories manufacturing Chinese medicines in Malaysia.

CONCLUSION

This report highlights the open and widespread availability of bear gall bladders, bile and derivatives in TCM shops at significant levels throughout all States in Malaysia. The study only reveals part of the full extent of bear trade in Malaysia, due to the clandestine and illegal nature of the trade.

Sun Bears hunted illegally in Malaysia supply locally-sourced bear parts and derivatives, while most imported products originated from China. Bear trade between Sabah, Sarawak and Peninsular Malaysia, and international trade openly violates Malaysian national laws and CITES regulations.

Strong enforcement actions are required to deter retailers from selling illegal bear parts and products. As this falls under legislations administered by MNRE and MOH, the relevant departments in both ministries need to work together to ensure that all bases are covered. Although the wildlife departments have commendably carried out some enforcement efforts based on information submitted from this survey, more frequent checks on such premises would send a strong message regarding any trade of bear bile. MOH also needs to play a more prominent role in ensuring that medical products containing illegal wildlife do not pass registration and that errant traders are duly punished.

Support from and engagement with the TCM community will be essential in attempts to reduce the trade in bear products, through reducing demand by promoting herbal alternatives and regulating the sale of endangered species and illegal products. A promising start was made when TRAFFIC was invited by the Federation of Chinese Physicians and Medicine Dealers Association of Malaysia to speak at the 12th World Congress on Traditional Chinese Medicine held in Kuching, Sarawak in 2012. Moving forward, TRAFFIC has re-opened discussions with the Federation to work closely and align messages against the unsustainable and illegal use of wildlife products in TCM.

RECOMMENDATIONS

To address the large-scale illegal trade in bear bile, bear gall bladders and bear products across Malaysia, TRAFFIC makes the following recommendations:

Legal and Policy Framework

- Consistency in legislation is recommended to ensure that all trade in bear parts and derivatives is effectively banned within Malaysia. This has already been addressed in wildlife laws. However, the *Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984)* should specifically include a clause ensuring that domestic and imported traditional medicines containing wildlife derivatives must adhere to wildlife regulations before being awarded Good Manufacturing Practice certification (which is mandatory for a manufacturing licence and product registration, and is applicable to importers and wholesalers as well as manufacturers), issued permits for sale of medicine, and/or granted product trade and consumption approvals.
- Sun Bears in Sarawak should be accorded the highest level of protection and listed as ‘Totally Protected’ under the *Sarawak Wildlife Protection Ordinance 1998*. This would result in higher penalties for offenders, creating greater deterrent effect, as well as stronger formal protection.
- MOH is recommended to recognise that some traditional medicine is prescribed in its raw form, which excludes them from enforcement under the *Sale of Drugs Act 1952 (Control of Drugs and Cosmetics Regulation 1984)* although they are sold as a medicine. TRAFFIC recommends that MOH and the Ministry of Natural Resources and Environment (MNRE) address this jointly.
- In Selangor, business permits of retailers found to be repeatedly flouting the *Wildlife Conservation Act 2010* and the *International Trade in Endangered Species Act 2008* by selling wildlife illegally or products containing wildlife parts can be suspended under the state government’s Cancellation of Licences in Aid of Wildlife (CLAW) programme. This novel programme is intended to aid both federal and state law enforcement agencies stop illegal wildlife trade and presents a strong deterrent effect, and should be considered by other states too.

Enforcement

- MOH is urged to improve the screening process when registering medicinal products containing animal derivatives. It is recommended that MOH’s pharmaceutical enforcement department be more vigilant when carrying out inspections and raids, for instance searching for products in Chinese language as a number of products are imported from China.
- Individuals and companies importing, collecting, selling, buying, transporting or keeping bear parts and derivatives are in violation of CITES and/or national laws (*Wildlife Conservation Act 2010*, *Sarawak Wildlife Protection Ordinance 1998*, *Sabah Wildlife Conservation Enactment 1997*, *International Trade in Endangered Species Act 2008*) and must be prosecuted and penalized to act as a deterrent and to demonstrate the Government’s commitment to stopping the illegal trade in endangered animals such as bears. Claiming that manufactured products contain bear bile, regardless of the actual contents, is also an offence under the *Wildlife Conservation Act 2010*.
- Collaboration between wildlife departments, the MOH pharmaceutical enforcement units and city council law enforcement units to carry out concerted and frequent checks and raids on TCM shops are required. Given the vast number of TCM practitioners throughout the country and differing jurisdictions, this approach capitalises on limited resources, enable unregistered medications containing protected wildlife, and wildlife parts in their raw form to be confiscated and offending businesses to be charged in court. This will also improve enforcement efforts at a local level and strengthen the message that selling illegal wildlife products is a serious offence considered by all arms of the Malaysian government.

- As TCM shops surveyed in the two East Malaysian states of Sabah and Sarawak that sold gall bladders sourced them from native Sun Bears, concerted enforcement efforts by the Sabah Wildlife Department and Sarawak Forest Corporation are needed to combat the poaching and trade of Sun Bears on Malaysian Borneo, and to prevent the illegal sourcing of bear parts by poachers to the TCM industry.
- MOH is urged to check on factories manufacturing Chinese medicines in Malaysia to ensure that legal standards are adhered to in the import of raw materials for the production of TCM products containing wildlife. More thorough background checks on such operations are recommended before they are granted manufacturing licences by MOH.
- MOH is urged to develop and implement a formal mechanism to regulate the dispensing activities of TCM medicine retailers, as these are currently not covered under existing legislations.

Co-ordination

- Closer co-operation is encouraged between government departments dealing with wildlife and health issues to promote efficiency in efforts to combat illegal trade in bear parts, derivatives and products. These should include the Department of Wildlife and National Parks, Sabah Wildlife Department, Sarawak Forest Department, Sarawak Forestry Corporation, the Traditional and Complementary Medicine Unit and the National Pharmaceutical Control Bureau of MOH, the Customs Department and local governments.
- Relevant government departments should form strategic alliances with NGOs, universities and other research centres to carry out monitoring, research and education efforts conducive to effective implementation of wildlife laws, including but not restricted to the testing of contents of *Xiongdan* pills and other products alleged to contain bear bile.
- Dialogue should be encouraged between government, NGO and TCM communities on issues of bear use in TCM, through forums such as the International Conference in Traditional Chinese Medicine.

Purchasing

- Wide-scale and sustained public education campaigns should be promoted to highlight issues of bear bile trade in TCM and to engage the public in responsible and legal purchasing of TCM products. The conservation and judicial consequences of purchasing bear products should be made clear.
- TCM practitioners and retailers should be encouraged to promote the use of herbal alternatives to bear products and advise consumers how to avoid using bear gall bladder, bile and products and why. The Federation of Chinese Physicians and Medicine Dealers Association of Malaysia is also urged to take a stance in opposing the use of bear parts and products in TCM.

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TRAFFIC REPORT

TRAFFIC, the wildlife trade monitoring network, is the leading non-governmental organization working globally on trade in wild animals and plants in the context of both biodiversity conservation and sustainable development.

For further information contact:
TRAFFIC

Southeast Asia Regional Office
Unit 3-2, 1st Floor
Jalan SS23/11, Taman SEA
47400 Petaling Jaya
Selangor, Malaysia
Telephone: (603) 7880 3940
Fax: (603) 7882 0171
Website: www.traffic.org

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